UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

WILLIAM E. BAZZELLE, SR., *individually and on behalf of all others similarly situated*,

Plaintiff,

-v-

NOVOCURE LIMITED, *et al.*,

Defendants.

1:23-cv-5146-GHW

MEMORANDUM OPINION & ORDER

GREGORY H. WOODS, United States District Judge:

I. INTRODUCTION

NovoCure Limited ("NovoCure") is a global oncology company that markets a cancer therapy called "Tumor Treating Fields" ("TTFields"). TTFields therapy is currently approved for treatment of certain brain and lung cancers, but NovoCure believes that it is more broadly applicable. NovoCure tested that hypothesis in a clinical trial called LUNAR, which was designed to measure TTFields' effectiveness in treating Non-Small Cell Lung Cancer ("NSCLC"), the most common form of lung cancer in the United States. When NovoCure and some of its executives ("Defendants") announced positive topline results from the LUNAR trial, NovoCure's stock price soared. But when Defendants revealed the full LUNAR data five months later, NovoCure's stock fell below its initial price.

Plaintiff, an investor in NovoCure, alleges that the company's stock price declined because Defendants' topline reports failed to disclose flaws in LUNAR's design that undermined the reliability and relevance of its results. Among other things, Plaintiff alleges that Defendants failed to disclose that LUNAR did not measure the presence of an important biomarker in nearly half of its patients' cancer cells, and that the majority of LUNAR's trial population did not receive treatment in

line with the evolving standard of care for patients with NSCLC. Plaintiff also faults LUNAR for not implementing a study design that would yield immediate industry and commercial uptake. Plaintiff claims that Defendants' statements were materially false or misleading in violation of Section 10(b) and 20(a) of the Securities Exchange Act of 1934. Defendants move to dismiss Plaintiff's claims pursuant to Fed. R. Civ. P. 12(b)(6), arguing that Plaintiff fails to allege that Defendants' statements were false or misleading and that Plaintiff fails to plead the requisite scienter.

Defendants' motion is granted on both grounds. Plaintiff's allegations are, at most, allegations that Defendants' clinical trial should have been designed differently, or that Plaintiff's interpretation of LUNAR's data is better than Defendants'. Scientific disputes like Plaintiff's are not actionable under Section 10(b). Moreover, Plaintiff fails to adequately allege that any of Defendants' statements were made with a wrongful state of mind. Defendants' motion to dismiss, accordingly, is GRANTED.

II. BACKGROUND

A. Facts[1]

1. NovoCure and Its Business

Defendant NovoCure Limited ("NovoCure") is a global oncology company incorporated in the Channel Islands and headquartered in Switzerland. AC ¶ 21. NovoCure markets a proprietary cancer therapy called "Tumor Treating Fields" ("TTFields"). *Id.* ¶ 2. TTFields therapy is administered using a wearable device called "Optune," *id.* ¶ 29, which emits "electrical pulses that theoretically disrupt cancer cells' ability to divide and proliferate," *id.* ¶¶ 2, 28. NovoCure generates revenues from TTFields "by charging monthly fees for the use of its TTFields devices." *Id.* ¶ 34.

[1] The facts are taken from the amended complaint, Dkt. No. 52 ("AC"), and are accepted as true for the purposes of this motion. *Town of Babylon v. Fed. Hous. Fin. Agency*, 699 F.3d 221, 227 (2d Cir. 2012). The Court also considers "statements or documents incorporated into the complaint by reference, legally required public disclosure documents filed with the SEC [Securities and Exchange Commission], and documents possessed by or known to the plaintiff and upon which it relied in bringing the suit." *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007).

TTFields are intended for use in conjunction with "standard cancer treatments, including chemotherapy and immunotherapy." *Id.* ¶ 2. They are currently approved "primarily . . . to treat adults with glioblastoma, the most prevalent type of brain cancer." *Id.* ¶¶ 2, 29. They are also approved for treatment of malignant pleural mesothelioma, a rare lung cancer linked to asbestos exposure. *Id.* ¶ 29. NovoCure has "hypothesized," however, that "TTFields therapy may be broadly applicable to [other] solid tumor cancers." *Id.* ¶ 32. NovoCure has "prioritized" expanding the use of TTFields therapy to other solid-tumor cancers, and has undertaken clinical trials to test the applicability of TTFields therapy to various solid-tumor cancers over the past several years. *See id.*

Relevant here, NovoCure has explored the possibility of expanding TTFields therapy to Non-Small Cell Lung Cancer ("NSCLC"). *Id.* ¶ 3. NSCLC is the most common form of lung cancer, and is "far more prevalent" than glioblastoma and malignant plural mesothelioma, *id.* ¶ 33, the cancers for which TTFields therapy is currently approved, *id.* ¶ 29. NovoCure established a trial called LUNAR to evaluate the effectiveness of TTFields in treating NSCLC. *Id.* ¶ 3. LUNAR allegedly "represented a key opportunity to significantly expand the reach of TTFields therapy." *Id.* ¶ 33.

2. The Individual Defendants

Three NovoCure employees (the "Individual Defendants," and together with NovoCure, "Defendants") are also named as defendants in this action. "Defendant William F. Doyle ('Doyle') is, and was at all relevant times, NovoCure's Executive Chairman and a Director." *Id.* ¶ 22. Defendant Asaf Danziger ("Danziger") "is, and was at all relevant times, NovoCure's CEO and a Director." *Id.* ¶ 23. And Defendant Ashley Cordova ("Cordova") "is, and was at all relevant times, NovoCure's CFO." *Id.* ¶ 24.

3. The LUNAR Trial

The LUNAR trial was conducted on a population of patients with stage four NSCLC. *Id.* ¶ 40. The patients' cancer had progressed to "at least one other part of [their] body" during their first round of treatment, or "first-line" treatment, with "platinum-based chemotherapy." *Id.* ¶ 40 & n.2. The LUNAR trial therefore "evaluated the use of TTFields therapy as a second-line therapy," following the patients' first-line treatment with platinum-based chemotherapy. *Id.* ¶ 40.

LUNAR was a "pivotal" trial. *Id.* ¶ 33. According to the AC, "clinical trials of medical devices such as Optune typically proceed in three phases known as 'pre-clinical,' 'pilot,' and 'pivotal.'" *Id.* ¶ 33 n.1. "[A] successful pivotal trial [is] required to obtain regulatory approval" for treatment using a medical device. *Id.*

The LUNAR trial was split into "two cohorts." *Id.* ¶ 42–43. The first cohort was designed to measure the effectiveness of receiving TTFields in conjunction with an immunotherapy called immune checkpoint inhibitors ("ICIs"), *id.* ¶¶ 4, 42, versus receiving ICIs alone, *id.* ¶ 41. The "experimental arm" of the ICI cohort received both TTFields and ICIs, and the "control arm" of the ICI cohort received ICIs alone. *Id.* ¶¶ 41–42. The second LUNAR cohort was designed to measure the effectiveness of receiving TTFields in conjunction with a chemotherapy drug called docetaxel, *id.* ¶¶ 4, 42, versus receiving docetaxel alone, *id.* ¶ 41. The "experimental arm" of the docetaxel cohort received both TTFields and docetaxel, and the "control arm" of the docetaxel cohort received docetaxel alone. *Id.* ¶¶ 41–42.

The "'primary endpoint' (*i.e.*, main objective) of the LUNAR trial" was for patients who received TTFields to "survive[] for a 'statistically significant' greater number of months" compared with "patients who did not receive TTFields therapy." *Id.* ¶ 41. For the purposes of LUNAR's "primary endpoint," therefore, the survival of patients who received TTFields in conjunction with either ICIs or docetaxel was measured against patients who received just ICIs or just docetaxel. *Id.*

The LUNAR trial also had two "secondary endpoints," or objectives. *Id.* ¶ 42. Those were to achieve statistically significant survival benefits for patients who received TTFields in each of LUNAR's two cohorts. One secondary endpoint was to achieve a statistically significant survival benefit from receiving "TTFields plus ICIs, versus ICIs alone," and the other secondary endpoint was to achieve a statistically significant survival benefit from receiving "TTFields plus docetaxel, versus docetaxel alone." *Id.*

"NovoCure began enrolling patients in the LUNAR trial in February 2017." *Id.* ¶ 44. NovoCure initially intended to enroll 534 patients, but in April 2021, the trial's independent data monitoring committee ("DMC")[2] "recommended a reduced sample size" of 276 patients, citing ethical concerns with continuing to randomize patients into LUNAR's control arms. *Id.* ¶¶ 44–45. "NovoCure adopted the DMC's recommendations, and ultimately completed enrollment of . . . 276 patients in November 2021." *Id.* ¶ 47. Patient follow-ups were completed in November 2022. *Id.*

4. Current Treatments for NSCLC

According to the AC, "[c]urrently approved treatments for NSCLC include platinum-based chemotherapy, taxane chemotherapy," and "more recently, ICIs." *Id.* ¶ 35. Docetaxel chemotherapy is a type of taxane chemotherapy. *Id.* ¶ 36. ICIs, on the other hand, are a type of immunotherapy that acts on a patient's "immune checkpoints," which aid the body's immune system, including its T-cells,[3] in differentiating between normal cells and cancer cells. *Id.* ¶ 37. ICIs aid the body's immune system in "attack[ing] [cancer] cells while leaving normal cells alone." *Id.* In the case of NSCLC, ICIs block a protein on the surface of the cancer cells from binding with "partner" proteins on the body's T-cells and sending a signal to those T-cells to stop attacking. *Id.*

[2] It is allegedly "typical in clinical trials" to have a DMC comprised of independent scientists that monitors the data and conducts interim analyses of the trial's "primary endpoint and safety." *Id.* ¶ 44 n.3.
[3] The AC does not define T-cells. According to the Cleveland Clinic, "T cells are a type of white blood cell called lymphocytes. They help your immune system to fight germs and protect you from disease." *T Cells*, CLEVELAND CLINIC, Jan. 17, 2023, https://my.clevelandclinic.org/health/body/24630-t-cells.

¶¶ 38–39. That protein is called "PD-L1." *Id.* ¶ 39. The AC alleges that "[t]he higher a patient's levels of PD-L1, the better ICIs will generally work." *Id.*

ICIs were "first approved to treat NSCLC in 2015 . . . as a second-line therapy in certain patients who had failed treatment with platinum-based chemotherapy." *Id.* ¶ 49. "[I]n October 2016, the FDA approved an ICI for use as a first-line therapy in certain NSCLC patients." *Id.* ¶ 50. At some point thereafter, it allegedly "became standard practice to test a patient's PD-L1 levels to determine how well ICIs would likely work." *Id.* Currently, ICIs are "general[ly] . . . given to patients whose PD-L1 score is greater than 1%." *Id.* ¶ 39.

The AC does not allege that it was standard practice to treat NSCLC patients with ICIs as part of their first-line treatment (and accordingly, to measure patients' PD-L1 levels as part of their first-line treatment) when LUNAR began enrolling patients. *See id.* ¶¶ 50–51; *see also id.* ¶ 84 (alleging that an analyst stated: "[I]t's my understanding, the LUNAR study was started before testing for PD-L1 status at baseline was . . . a thing." (alterations omitted)). First-line treatment with ICIs obtained regulatory approval in October 2016, and LUNAR began enrolling patients in February 2017. *Id.* ¶¶ 44, 50. LUNAR randomized its patients into its four trial arms, *see id.* ¶ 44, but it did not randomize its patients into each arm in a way that assigned them "roughly equal numbers of patients with similar [PD-L1 scores]," *id.* ¶ 59 & n.4.[4] The AC alleges that "a key question among analysts and investors while awaiting the full LUNAR data was whether LUNAR's results had been skewed by imbalances in patients' PD-L1 status among the trial's four subgroups." *Id.* ¶ 59.

5. Defendants Report on LUNAR's Topline Results

The alleged Class Period in this case began on January 5, 2023, when NovoCure issued a press release "announcing positive topline results for the LUNAR trial." *Id.* ¶ 52. The press release

[4] The practice of randomizing patients in accordance with specific characteristics that are "predicted to affect . . . trial results" is called "stratification." *Id.* ¶ 59 n.4.

stated that LUNAR had "met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in overall survival over standard therapies alone." *Id.* As for LUNAR's secondary endpoints, the press release stated that patients treated with TTFields and ICIs "showed a statistically significant . . . improvement in overall survival" when compared with "those treated with [ICIs] alone." *Id.* ¶ 53 (alterations in original). The docetaxel cohort, on the other hand, did not reach statistical significance, though "there was a positive trend in overall survival when patients were treated with TTFields and docetaxel versus docetaxel alone." *Id.* ¶ 54. "The press release explained that '[t]he full LUNAR data [would] be presented at a future medical congress." *Id.* (alterations in original). Plaintiff does not dispute the accuracy of these statements in the press release. *See* Dkt. No. 69 at 15 ("Opp.").

In the same press release, NovoCure described LUNAR's results as "clinically meaningful" and "profound." AC ¶ 53. Defendants continued to report on these topline results in press releases, SEC filings, earning calls, and investor presentations between January 5, 2023 and May 4, 2023, *id.* ¶¶ 73–108, and continued to characterize LUNAR's results as "profound" and "clinically meaningful," *id.* ¶¶ 73, 76, 80, 88, 92, 94, 102, 104, as well as calling the results "groundbreaking," a "key achievement," and a "crucial finding," *id.* ¶¶ 94–95, 102.

Defendants also stated in the January 5, 2023 press release that "[p]atient enrollment" in LUNAR "was well balanced between the ICI and docetaxel cohorts of the experimental and control arms." *Id.* ¶ 73. They made similar or identical statements on multiple occasions following the press conference. *Id.* ¶¶ 84, 92, 99. And in NovoCure's Form 10-K filed with the SEC on February 23, 2023, Defendants stated that "[w]e believe our protocol incorporates the evolving standard of care for second-line treatment of NSCLC." *Id.* ¶ 92.

In subsequent reports on LUNAR's topline results, Defendants Doyle and Danziger made additional "optimistic statements" about LUNAR's trial results. Opp. at 34. In statements on

January 9 and 10, 2023, Defendant Doyle stated, among other things, that LUNAR marks "the beginning of a transformational period," that NovoCure was "energized by the prospect of treating tens of thousands of patients who could benefit from [TTFields]," and that NovoCure was "standing on the threshold of the opportunity to treat many, many more patients." AC ¶¶ 78, 82. And in a February 23, 2023 statement, Defendant Danziger stated that "[t]he positive top-line readout from the pivotal trial marked the beginning of a transformational 24 months for Novo[C]ure." *Id.* ¶ 90.

Finally, on at least three occasions following the January 5, 2023 press release, Defendant Doyle fielded questions from analysts and investors about the patient characteristics of LUNAR patients. First, during a January 10, 2023 investor conference, an analyst asked: "did you guys measure PD-[L]1 status at baseline?" *Id.* ¶ 84. Doyle did not respond directly to that question. His response stated, among other things, that PD-L1 status "has not shown any relevance in second line," that "there was nothing unusual about the control group," that LUNAR's "arms were well balanced," and that the analyst's question was a "red herring." *Id.* Second, during a February 23, 2023 conference call, an analyst asked: "Can you talk about our confidence level that the active and control arms in the study are balanced in terms of patient characteristics?" *Id.* ¶ 99. Doyle responded saying, among other things, that "the arms were well balanced in terms of numbers" and that "all the indications . . . show balance." *Id.* And third, during a May 4, 2023 conference call, an analyst asked whether NovoCure's upcoming presentation of the full LUNAR data would "address" questions "related to PD-L1 status," including "whether you have data on PD-L1 status for a large percentage of the patients" and "whether there was an imbalance." *Id.* ¶ 108. Doyle responded that "we would expect to address all the issues with respect to balance and PD-L1 status at that time." *Id.*

6. NovoCure Reports the Full LUNAR Data

The alleged Class Period in this case came to a close on June 6, 2023, when NovoCure revealed the full LUNAR data in a press release, two presentations at the annual meeting of the American Society of Clinical Oncology ("ASCO"), and a "NovoCure . . . investor event." *Id.* ¶¶ 110, 113–15. The data showed that patients who received TTFields therapy together with standard therapies lived 3.3 months longer than patients who did not receive TTFields therapy. *Id.* ¶ 110. This "survival benefit" was statistically significant, *id.* ¶¶ 52, 110, meaning LUNAR had achieved its primary endpoint, *id.* ¶ 51. The data also showed that patients who received TTFields therapy in conjunction with ICIs lived 7.7 months longer than patients who received only ICIs. *Id.* ¶ 110. This too was statistically significant, meaning LUNAR had achieved its secondary endpoint with respect to the ICI cohort. *Id.* ¶¶ 51, 53. On the other hand, patients who received TTFields therapy together with docetaxel lived 2.4 months longer than patients who received only docetaxel, "which fell short of statistical significance." *Id.* ¶ 110.

Other aspects of the LUNAR data were more concerning to investors. NovoCure's press release revealed that LUNAR had collected PD-L1 data from only 55% of its patients. *Id.* ¶ 111. Moreover, only 31% patients in the trial had previously been treated with ICIs as part of their first-line therapy, "comprising 58% of patients randomized to the docetaxel cohort and just 2% of patients randomized to the ICI cohort." *Id.* (quotations omitted). This concerned investors because the standard of care for NSCLC had evolved to incorporate ICIs in first-line treatment, *id.* ¶ 115, and because LUNAR's ICI cohort was the cohort that appeared to show the most promising results, *see id.* ¶ 119.

NovoCure's share price on the day of these disclosures fell more than 43%. *Id.* ¶ 117. The shares had closed at $82.51 on June 5, 2023, and closed at $47.00 per share on June 6, 2023. *Id.*

7. The Challenged Statements

The Court has already previewed the statements Plaintiff challenges in this action. The statements fall into five categories:[5] (1) statements characterizing the importance and relevance of LUNAR's results, including that they were "clinically meaningful" and "profound";[6] (2) Defendants'

[5] The Court is guided by the Appendix attached to Plaintiff's opposition brief, where he listed the challenged statements in the AC and "highlighted . . . the specific portions of the statements alleged to be actionable." Dkt. No. 70-1 at 1 n.2.

[6] This category consists of the following statements: AC ¶¶ 73 (". . . the LUNAR study met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in overall survival over standard therapies alone"), 73 ("The LUNAR study also showed a statistically significant and clinically meaningful improvement in overall survival when patients were treated with TTFields and immune checkpoint inhibitors (ICI), as compared to those treated with immune checkpoint inhibitors alone . . ."), 74 ("We are also pleased by the profound performance of the TTFields together with immunotherapy . . ."), 76 ("The LUNAR study met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in overall survival. The LUNAR study showed a statistically significant and clinically meaningful improvement in overall survival when patients were treated with TTFields and immune checkpoint inhibitors (ICI), as compared to those treated with immune checkpoint inhibitors alone . . ."), 80 (". . . the result for the patients who were treated with Tumor Treating Fields and docetaxel was a positive trend. A clinically meaningful outcome, but it didn't reach statistical significance in the subgroup. But in the Tumor Treating Fields plus immunotherapy arm, we achieved what we said in the press release was a profound result."), 84 (". . . this is a well-powered, randomized study where we showed a profound benefit."), 88 ("The LUNAR study met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in overall survival over standard therapies (either immune checkpoint inhibitors or docetaxel) alone. The LUNAR study also showed a statistically significant and clinically meaningful improvement in overall survival when patients were treated with TTFields and immune checkpoint inhibitors ("ICI"), as compared to those treated with ICI alone, and a positive trend in overall survival when patients were treated with TTFields and docetaxel versus docetaxel alone . . ."), 92 ("We believe our protocol incorporates the evolving standard of care for second-line treatment of NSCLC. TTFields is intended principally for use in combination with other standard-of-care treatments, and LUNAR was designed to generate data that contemplates multiple outcomes, all of which we believe will be clinically meaningful . . ."), 92 (". . . the LUNAR study met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in overall survival for patients treated with TTFields and standard therapies compared to those treated with standard therapies alone. The LUNAR study also showed a statistically significant and clinically meaningful improvement in overall survival when patients were treated with TTFields and immune checkpoint inhibitors, as compared to those treated with immune checkpoint inhibitor alone . . ."), 94 ("LUNAR met its primary endpoint, demonstrating a statistically significant and clinically meaningful extension in overall survival for patients treated with TTFields together with standard therapies. Further, we saw a statistically significant and clinically meaningful extension in overall survival for patients treated with TTFields and immune checkpoint inhibitors versus immune checkpoint inhibitors alone, and a positive trend in overall survival for patients treated with TTFields and docetaxel versus docetaxel alone. We believe these data represent a crucial finding for patients diagnosed with Stage 4 non-small cell lung cancer . . ."), 95 ("LUNAR is a key achievement for NovoCure. LUNAR is our first pivotal study completed with immunotherapies and our first pivotal study treating solid tumors outside of the brain."), 97 (". . . the data, as we said, are profound when TTFields are combined with checkpoint inhibitors . . ."), 102 ("We are eager to share our groundbreaking data at the 2023 ASCO Annual Meeting . . ."), 102 (". . . the LUNAR clinical trial met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in overall survival when TTFields therapy was added to standard pharmacological therapies compared to standard pharmacological therapies alone."), 104 ("Patients treated with TTFields and standard therapies demonstrated a statistically significant and clinically meaningful improvement in overall survival over standard therapies alone. The LUNAR study also showed a statistically significant and clinically meaningful improvement in overall survival when patients were treated with TTFields and immune checkpoint inhibitors, as compared to those treated with immune checkpoint inhibitors alone . . ."), 106 ("LUNAR demonstrated a profound benefit when TTFields therapy was combined with immunotherapy meeting powered secondary endpoints evaluating overall survival of patients treated with TTFields and a checkpoint inhibitor versus a checkpoint inhibitor alone.").

statement in NovoCure's Form 10-K that "[w]e believe our protocol incorporates the evolving standard of care for second-line treatment of NSCLC";[7] (3) Doyle's statement that "we would expect to address all the issues" at the upcoming ASCO meeting;[8] (4) Defendants' statements that LUNAR's trial arms were "well balanced";[9] (5) Doyle's response to an analyst's questions about PD-

[7] In full, Defendants stated:

> We believe our protocol [for the LUNAR trial] incorporates the evolving standard of care for second-line treatment of NSCLC. TTFields is intended principally for use in combination with other standard-of-care treatments, and LUNAR was designed to generate data that contemplates multiple outcomes, all of which we believe will be clinically meaningful.

AC ¶ 92.

[8] The exchange, in full, went as follows. An analyst asked:

> And then just a question on the LUNAR presentation. Some of the questions are unknowns or related to PD-L1 status, clearly, whether you have data on PD-L1 status for a large percentage of the patients, whether there was an imbalance, do you expect that the presentation will address these questions such that there won't be ambiguity about the results for the [ICI] groups following ASCO[?]

AC ¶ 108 (alterations in complaint). Doyle responded:

> So first and foremost, we're looking forward to seeing everybody in June. Following the presentation, we will also have an investor meeting that will include KOLs, investigators as well as NovoCure personnel. And we would expect to address all the issues with respect to balance and PD-L1 status at that time.

Id.

[9] This category consists of the following statements: AC ¶¶ 73 ("Patient enrollment was well balanced between the ICI and docetaxel cohorts of the experimental and control arms, and control arms performed in line with prior studies."), 84 ("So these arms were well balanced and the controls behaved as expected, in line with prior studies."), 92 ("Patient enrollment was well balanced between the immune checkpoint inhibitor and docetaxel cohorts of the experimental and control arms, and the control arms performed in line with prior studies."), 99 (". . . the control groups behaved as expected and . . . the arms were well balanced in terms of numbers."), 99 (". . . all the indications . . . show balance.).

L1 scores at the January 10, 2023 press conference;[10] and (6) Defendants' optimistic statements about the future of TTFields as a result of LUNAR's results.[11]

B. Procedural History

This action commenced on June 19, 2023. Dkt. No. 1. The Court granted Plaintiff's motion for appointment as Lead Plaintiff on August 29, 2023. Dkt. No. 45. Plaintiff filed the operative AC on November 13, 2023. Dkt. No. 52.

On March 4, 2024, Defendants moved to dismiss the AC. Dkt. No. 63; Dkt. No. 64 ("Mem."); Dkt. No. 77 ("Reply"). Defendants filed 24 exhibits in connection with their motion to dismiss, which they argued were either incorporated by reference in the complaint, integral to the complaint, or subject to judicial notice. *See* Dkt. No. 65 ("Brody Decl."). On May 6, 2024, Plaintiff

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[10] The exchange, in full, went as follows. An analyst asked:

> So it's my understanding, the LUNAR study was started before PD-1 status at baseline was I guess, a thing. Is that correct? And if it's so, did you guys measure PD-1 status at baseline?

AC ¶ 84; Dkt. No. 65-3. Doyle responded:

> So the answer to your questions, and I know why you asked this, right? There was a short note yesterday about PD-1 status. So the first thing I'll remind you, this is a trial in the second line, not the first line. And PD-1 status has not shown any relevance in second line.
>
> Secondly, I will tell you that when we—and I didn't mention this in the presentation. But there was nothing unusual about the control group. So when you report top line data, it's very encouraging to hear that the trial was successful in the top line. But then you have to ask what about the controls. Was there anything funky about the controls. So these arms were well balanced and the controls behaved as expected, in line with prior studies. So there was nothing funky here. So this is a well-powered, randomized study where we showed a profound benefit. And the full data, including PD-1 status will be presented later. But I think that's a red herring.

AC ¶ 84; Dkt. No. 65-3.

[11] This category consists of the following statements: AC ¶¶ 78 ("The successful LUNAR study marks the beginning of a transformational period where we anticipate final data from multiple pivotal trials. We are eager to reach these clinical milestones and energized by the prospect of treating tens of thousands of patients who could benefit from Tumor Treating Fields."), 82 (". . . we are now standing on the threshold of the opportunity to treat many, many, many more patients by extending the reach of our platform."), 82 ("We couldn't be more excited that the promise to bring Tumor Treating Fields into new indications is here."), 90 ("The positive top-line readout from the pivotal LUNAR study marked the beginning of a transformational 24 months for Novocure. LUNAR is the first of four pivotal studies we expect to read out in the next two years which could dramatically increase the number of patients eligible for Tumor Treating Fields."), 94 ("We believe the LUNAR data have the potential to transform the treatment paradigm for these patients, and more generally point to the future of solid tumor therapy.").

filed his opposition to Defendants' motion to dismiss. Dkt. No. 69 ("Opp."). He filed one exhibit in connection with his opposition brief. *See* Dkt. No. 70 ("Boardman Decl.").

Also on May 6, 2024, Plaintiff moved to strike 17 of the 24 exhibits connected to Defendants' motion to dismiss. Dkt. No. 71; Dkt. No. 72 ("Strike Mem."); Dkt. No. 76 ("Strike Opp."); Dkt. No. 78 ("Strike Reply"); Dkt. No. 79 ("Supp. Boardman Decl.").[12]

III. MOTION TO STRIKE

Before turning to Defendants' motion to dismiss, the Court first addresses, and denies, Plaintiff's motion to strike the exhibits submitted in connection with Defendants' motion to dismiss. Plaintiff's motion is denied because it is "procedurally improper." *In re AppHarvest Sec. Litig.*, 684 F. Supp. 3d 201, 238 (S.D.N.Y. 2023). Fed. R. Civ. P. 12(f) provides that "[t]he court may strike from a *pleading* an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f) (emphasis added). "Fed. R. Civ. P. 7 excludes motions from the definition of pleadings, and courts in this district have held that Rule 12(f) does not authorize this court to strike documents other than pleadings." *Honig v. Hansen*, 2021 WL 4651475, at *3 (S.D.N.Y. Oct. 6, 2021) (collecting cases). Plaintiff argues that, despite the clear language in the Federal Rules, the Court may strike Defendants' exhibits because district courts have "'inherent authority to strike any filed paper' they find 'improper.'" Strike Mem. at 3 (quoting *Nat. Res. Def. Council v. U.S. Food & Drug Admin.*, 884 F. Supp. 2d 108, 115 n.5 (S.D.N.Y. 2012)). Plaintiff infers this authority from a line of cases quoting from *Sierra v. United States*, a case which did state, after quoting from Rule 12(f), that "[a] court has inherent authority to strike any filed paper which it determines to be abusive or otherwise improper under the circumstances." No. 97-cv-9329 (RWS), 1998 WL 599715, at *9 (S.D.N.Y. Sept. 10, 1998). But *Sierra* denied the plaintiff's motion to strike because the motion

[12] Plaintiff later rescinded his motion to strike with respect to two of those exhibits. Strike Reply at 2 n.2.

asked the court to strike a document that was "not a pleading." *Id.* (observing that "Rule 12(f) does not authorize this court to strike documents other than pleadings"). The Court declines to infer from *Sierra* a general rule that it may strike any document that "find[s] improper." Strike Mem. at 3 (quotations omitted). Plaintiff's motion to strike Defendants' exhibits is therefore denied. *In re AppHarvest*, 684 F. Supp. 3d at 238; *Honig*, 2021 WL 4651475, at *3.

Still, as it always does, the Court examines Defendants' exhibits to determine whether they are properly considered to resolve this motion to dismiss. *See, e.g.*, *Lynch v. City of New York*, 952 F.3d 67, 79 (2d Cir. 2020) (evaluating whether document could be considered on motion to dismiss).[13] In addition to the allegations in the complaint, the Court "may consider any written instrument attached to the complaint, statements or documents incorporated into the complaint by reference, legally required public disclosure documents filed with the SEC, and documents possessed by or known to the plaintiff and upon which it relied in bringing the suit." *ATSI*, 493 F.3d at 98. The Court may also consider "documents that, although not incorporated by reference, are 'integral' to the complaint." *Sira v. Morton*, 380 F.3d 57, 67 (2d Cir. 2004). A document is "integral to the complaint" where the complaint "relies heavily upon its terms and effect." *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 153 (2d Cir. 2002) (quotations omitted). Finally, the Court may consider "matters of which judicial notice may be taken." *Goel v. Bunge, Ltd.*, 820 F.3d 554, 559 (2d Cir. 2016) (citation omitted). "It is proper to take judicial notice of the *fact* that press coverage, prior lawsuits, or regulatory filings contained certain information, without regard to the truth of their contents." *Arkansas Pub. Emps. Ret. Sys. v. Bristol-Myers Squibb Co.*, 28 F.4th 343, 352 (2d Cir. 2022) (emphasis in original, other alterations and quotation omitted).

[13] This is the proper question, which Plaintiff improperly framed as a motion to strike.

Defendants' exhibits are properly considered "in order to determine what statements they contained." *Roth v. Jennings*, 489 F.3d 499, 509 (2d Cir. 2007) (cleaned up). The AC incorporates by reference the NovoCure press releases attached to the Brody Declaration as Exhibits 1, 2, 3, 4, and 7 and the transcripts of NovoCure's earnings calls attached as Exhibits 6 and 9 because the AC "quote[s] from [them] extensively" in alleging that Defendants made fraudulent statements. *Sun v. TAL Educ. Grp.*, No. 22-cv-01015 (ALC), 2023 WL 6394413, at *1 n.1 (S.D.N.Y. Sept. 29, 2023) (finding complaint alleging securities fraud incorporated by reference "news releases, financial reports, and transcripts of earnings calls"); AC ¶¶ 73, 74, 76, 78, 80, 82, 84, 88, 90, 94, 95, 97, 99, 102, 106, 108. The AC incorporates by reference NovoCure's Form 8-K filed with the SEC on June 6, 2023, attached as Exhibit 10, for the same reason. As Plaintiff concedes, the AC quotes from that filing extensively in alleging facts about Defendants' corrective disclosure. AC ¶ 110; *see* Strike Opp. at 2 n.2 (rescinding motion to strike Exhibit 10). The AC also incorporates by reference the analyst reports discussing the LUNAR trial attached as Exhibits 11, 14, 15, and 16 because it quotes and cites from them extensively in alleging that "[t]he LUNAR trial suffered from serious flaws." AC ¶¶ 60–62, 94, 113, 118–19, 132; *see Sun*, 2023 WL 6394413, at *1 n.1. The PowerPoint presentation attached as Exhibit 12 is integral to the AC because the AC "relies heavily upon its terms and effect," *Chambers*, 282 F.3d at 153 (quotation omitted), as Defendants employed those slides to present their corrective disclosure of the full LUNAR data on June 6, 2023, *see Tung v. Bristol-Myers Squibb Co.*, No. 18-cv-01611 (MKV), 2020 WL 5849220, at *6 (S.D.N.Y. Sept. 30, 2020), *aff'd sub nom.* 28 F.4th 343 (2d Cir. 2022) (considering slides used in presentation of clinical trial data at a conference where the presentation was "mention[ed]" in the complaint); AC ¶ 113; *see generally id.* ¶¶ 110–17.

The Court may judicially notice NovoCure's SEC filings attached as Exhibits 5, 8, 20, 21, 22, 23, and 24, though only "to determine what statements they contain[]" rather than "for the truth of

the matters asserted" within them. *Roth*, 489 F.3d at 509 (cleaned up); *see also* AC ¶¶ 92, 104, 110, 141 (referencing these SEC filings). The Court may also judicially notice the descriptions of LUNAR's protocol published on clinicaltrials.gov, an official website of the United States National Institutes of Health, attached as Exhibit 13, as those descriptions were "published by government sources from which the Court may appropriately take judicial notice." *Abely v. Aeterna Zentaris Inc.*, No. 12-cv-4711 PKC, 2013 WL 2399869, at *13 (S.D.N.Y. May 29, 2013) (judicially noticing trial protocol descriptions published on clinicaltrials.gov). Finally, the Court may judicially notice the prescription labels published on accessdata.fda.gov, an official website of the United States Food and Drug Administration, attached as Exhibits 17, 18, and 19, for the same reason. *Gale v. Smith & Nephew, Inc.*, 989 F. Supp. 2d 243, 246 n.2 (S.D.N.Y. 2013) (judicially noticing "FDA public records" published on accessdata.fda.gov).

Plaintiff also filed an exhibit in connection with his opposition to Defendants' motion to dismiss. The exhibit is an article in a publication called *The Oncologist*. Boardman Decl., Ex. 2. The article is not referenced in the AC and is not integral to it. Accordingly, the Court does not consider its contents. *See, e.g.*, *United States ex rel. Foreman v. AECOM*, 19 F.4th 85, 108–09 (2d Cir. 2021).

IV. MOTION TO DISMISS PURSUANT TO FED. R. CIV. P. 12(b)(6)

A. Legal Standard

Turning now to the substance of Plaintiff's claims: Defendants' motion to dismiss the AC pursuant to Fed. R. Civ. P. 12(b)(6) is granted. To survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6), "a complaint must allege sufficient facts, taken as true, to state a plausible claim for relief." *Johnson v. Priceline.com, Inc.*, 711 F.3d 271, 275 (2d Cir. 2013) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555–56 (2007)). To determine plausibility, courts follow a "two-pronged approach." *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). "First, although a court must accept as true all of the allegations contained in a complaint, that tenet is inapplicable to legal conclusions, and threadbare recitals of the

elements of a cause of action, supported by mere conclusory statements, do not suffice." *Harris v. Mills*, 572 F.3d 66, 72 (2d Cir. 2009) (alterations and internal quotation marks omitted). Second, a court determines "whether the 'well-pleaded factual allegations,' assumed to be true, 'plausibly give rise to an entitlement to relief.'" *Hayden v. Paterson*, 594 F.3d 150, 161 (2d Cir. 2010) (quoting *Iqbal*, 556 U.S. at 679). Determining whether a complaint states a plausible claim is a "context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679.

Securities fraud claims are also subject to the heightened pleading requirements of Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act (the "PSLRA"). Rule 9(b) requires a party "alleging fraud or mistake" to "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). To satisfy this requirement, the complaint must "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *ATSI*, 493 F.3d at 99 (citation omitted). "Allegations that are conclusory or unsupported by factual assertions are insufficient." *Id.* (citation omitted). Moreover, under the PSLRA, plaintiffs must specify "each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). Plaintiffs must therefore "do more than say that the statements . . . were false and misleading; they must demonstrate with specificity why and how that is so." *Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004).

B. Section 10(b) and Rule 10b-5 Liability

The AC fails to allege that Defendants' statements were made in violation of federal securities laws. Under Section 10(b) and Rule 10b-5, it is unlawful to "make any untrue statement of

a material fact or to omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading[.]" 17 C.F.R. § 240.10b-5(b); *see also* 15 U.S.C. § 78j(b). To survive a defendant's motion to dismiss a claim brought under Section 10(b) and Rule 10b-5, a plaintiff must plausibly plead the following elements: "(1) a material misrepresentation (or omission); (2) scienter, *i.e.*, a wrongful state of mind; (3) a connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation." *Kleinman v. Elan Corp., plc*, 706 F.3d 145, 152 (2d Cir. 2013) (citing *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 341–42 (2005)). Defendants argue that the AC fails to adequately plead the first and second elements. The Court agrees.

1. False or Misleading Statements or Omissions

a. Legal Standard

To satisfy the first element, Plaintiff must allege that Defendants made actionable misstatements or omissions under Rule 10b-5. "A statement is misleading if a reasonable investor would have received a false impression from the statement." *Freudenberg v. E*Trade Fin. Corp.*, 712 F. Supp. 2d 171, 180 (S.D.N.Y. 2010) (citation omitted). "Silence, absent a duty to disclose, is not misleading under Rule 10b-5," *Macquarie Infrastructure Corp. v. Moab Partners, L.P.*, 601 U.S. 257, 265 (2024) (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 239 n.17 (1988)), and "Section 10(b) 'do[es] not create an affirmative duty to disclose any and all material information,'" *Arkansas Pub. Emps. Ret. Sys.*, 28 F.4th at 352 (quoting *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011)). "Just because 'a reasonable investor would very much like to know [a] fact' does not create any obligation to speak up." *Id.* at 353 (quoting *Dalberth v. Xerox Corp.*, 766 F.3d 172, 183 (2d Cir. 2014)). "Disclosure is necessary only if there is a duty to disclose or 'when necessary to make statements made, in the light of the circumstances under which they were made, not misleading.'" *Id.* (quoting *Kleinman*, 706 F.3d at 153)).

"[S]o-called 'half-truths'—literally true statements that create a materially misleading impression—will support claims for securities fraud." *SEC v. Gabelli*, 653 F.3d 49, 57 (2d Cir. 2011), *rev'd and remanded on other grounds*, 568 U.S. 442 (2013). "The literal truth of an isolated statement is insufficient; the proper inquiry requires an examination of defendants' representations, taken together and in context." *In re Morgan Stanley Info. Fund Sec. Litig.*, 592 F.3d 347, 366 (2d Cir. 2010) (internal quotation marks omitted). The key is the "presence of a prior statement that otherwise is or will become materially misleading" because of the omission. *DoubleLine Cap. LP v. Construtora Norberto Odebrecht, S.A.*, 413 F. Supp. 3d 187, 206 (S.D.N.Y. 2019).

Misrepresentations or omissions must also be material if they are to be actionable under Section 10(b). An omission is material if there is "a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *Levinson*, 485 U.S. at 240 (quoting *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976)). "At the pleading stage, a plaintiff satisfies the materiality requirement of Rule 10b-5 by alleging a statement or omission that a reasonable investor would have considered significant in making investment decisions." *Caiola v. Citibank, N.A., N.Y.*, 295 F.3d 312, 329 (2d Cir. 2002) (quotation omitted).

i. Statements of Opinion

"[S]ubjective statements of opinion are generally not actionable as fraud." *Afr. v. Jianpu Tech. Inc.*, 2022 WL 4537973, at *5 (S.D.N.Y. Sept. 28, 2022) (quoting *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 528 (S.D.N.Y. 2015), *aff'd sub nom. Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016)). It is "no small task for an investor" to meet the standard for pleading an actionable statement of opinion. *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 194 (2015). Investors who hear or read statements of opinion "take[] into account the customs and practices of the relevant industry."

Id. at 190. "So an omission that renders misleading a statement of opinion when viewed in a vacuum may not do so once that statement is considered, as is appropriate, in a broader frame." *Id.*

Nonetheless, an opinion statement may give rise to liability if "the speaker did not hold the belief she professed." *Tongue*, 816 F.3d at 210 (quoting *Omnicare*, 575 U.S. at 185–86). "It is not sufficient for these purposes to allege that an opinion was unreasonable, irrational, excessively optimistic, [or] not borne out by subsequent events." *Lopez v. Ctpartners Exec. Search Inc.*, 173 F. Supp. 3d 12, 24 (S.D.N.Y. 2016) (quotation omitted). The Second Circuit has firmly rejected the "fraud by hindsight" approach. *See Stevelman v. Alias Rsch, Inc.*, 174 F.3d 79, 85 (2d Cir. 1999).

Opinion statements can also give rise to liability even when they are "sincerely held." *Tongue*, 816 F.3d at 210. There are two distinct ways in which this can occur. First, an opinion statement may be actionable if the speaker supplies a "supporting fact" that is "untrue." *Omnicare*, 575 U.S. at 186. Second, an opinion statement may be actionable if it "omits material facts about the [speaker's] inquiry into or knowledge concerning statement of opinion." *Id.* at 189. That is because a reasonable investor "expects not just that [the speaker] believes the opinion (however irrationally), but that it fairly aligns with the information in the issuer's possession at the time." *Id.* Still, the Supreme Court has "cautioned against an overly expansive reading of this standard, noting that '[r]easonable investors understand that opinions sometimes rest on a weighing of competing facts,' and adding that '[a] reasonable investor does not expect that *every* fact known to [a speaker] supports its opinion statements.'" *Tongue*, 816 F.3d at 210 (quoting *Omnicare*, 575 U.S. at 189–90). Thus, a statement of opinion "is not necessarily misleading when an issuer knows, but fails to disclose, some fact cutting the other way." *Id.* (quoting *Omnicare*, 575 U.S. at 194). The "core inquiry is whether the omitted facts would 'conflict with what a reasonable investor would take from the statement itself.'" *Id.* (quoting *Omnicare*, 575 U.S. at 194).

Relevant here, when a speaker states an opinion "about the proper interpretation of data" in a clinical trial, that statement is "affirmatively misleading" only if it "expressed an interpretation of the data that was objectively irrational or unreasonable when [it was] made." *In Re Philip Morris Int'l Inc. Sec. Litig.*, 89 F.4th 408, 422–23 (2d Cir. 2023) (quotations omitted). And it is "misleading by omission . . . only when the omitted contrary facts *substantially undermine* the conclusion that a *reasonable investor* would reach from the statement." *Id.* at 423 (emphases in original, quotations and alterations omitted). In either case, moreover, it does not suffice merely to allege a "competing analysis or interpretation of the data." *Kleinman*, 706 F.3d at 154. The Second Circuit has repeatedly "rejected as a basis for liability" allegations that "are little more than a dispute about the proper interpretation of data." *Tongue*, 816 F.3d at 214 (citing *Kleinman*, 706 F.3d at 154–55). "That is, where plaintiffs (and others) take issue with a defendant's view regarding the results of the defendant's scientific studies, but the defendant's competing analysis or interpretation of data is itself reasonable, there is no false statement." *In Re Philip Morris*, 89 F.4th at 420 (quotations and alterations omitted).

ii. Corporate Optimism and Puffery

General statements of optimism and puffery are not actionable under federal securities laws because they are not "sufficiently specific that a reasonable investor could rely on [them] as a 'guarantee of some concrete fact or outcome.'" *Lopez*, 173 F. Supp. 3d at 29 (quoting *City of Pontiac Policemen's & Firemen's Ret. Sys. v. UBS AG*, 752 F.3d 173, 185 (2d Cir. 2014)); *see also In re Vale*, No. 1:15-cv-9539, 2017 WL 1102666, at *22 (S.D.N.Y. Mar. 23, 2017) (statements regarding "what Vale is 'seeking' to do, what it is 'committed' to doing, what it is 'focused on,' what it is 'aiming' to do, and what its 'priorities' are" were nonactionable). Even "misguided optimism is not a cause of action, and does not support an inference of fraud," because, as stated above, the Second Circuit has "rejected the legitimacy of 'alleging fraud by hindsight.'" *Shields v. Citytrust Bancorp, Inc.*, 25 F.3d

1124, 1129 (2d Cir. 1994) (citing *Denny v. Barber*, 576 F.2d 465, 470 (2d Cir. 1978)). Allegations that a defendant should have been "more alert and more skeptical" are insufficient; speakers are "not required to take a gloomy, fearful or defeatist view of the future." *Id.* at 1129–30.

Still, like opinion statements, statements of optimism and puffery can be actionable where they "contradict facts that are known to a defendant," *In re Virtus Inv. Partners, Inc. Sec. Litig.*, 195 F. Supp. 3d 528, 537 (S.D.N.Y. 2016), or where they amount to "'misrepresentations of existing facts' that were made even though the speaker 'knew that the contrary was true,'" *Galestan v. OneMain Holdings, Inc.*, 348 F. Supp. 3d 282, 298 (quoting *Novak v. Kasak*, 216 F.3d 300, 315 (2d Cir. 2000)).

b. Application

i. Statements that LUNAR's Results Were "Clinically Meaningful," "Profound," "Groundbreaking," a "Crucial Finding" and a "Key Achievement"

The various terms Defendants used to laud LUNAR and its topline results—"clinically meaningful," "profound," "groundbreaking," "crucial finding," and "key achievement"—are not alleged to be misleading because Plaintiff's allegations as to their falsity are no more than "non-actionable critique[s] of [Defendants'] trial design." *Abely*, 2013 WL 2399869, at *8. It is very well settled that "disagreements over a study's methodology do not, standing alone, raise an inference of securities fraud." *Id.* at *9; *accord, e.g.*, *In re Keryx Biopharmaceuticals, Inc., Sec. Litig.*, No. 13-cv-1307 (KBF), 2014 WL 585658, at *10 (S.D.N.Y. Feb. 14, 2014), at *1 (explaining that securities laws are not "a tool to second guess how clinical trials are designed and managed"); *Cachia v. Bellus Health Inc.*, No. 21-cv-02278 (GBD), 2022 WL 4367444, at *5 (S.D.N.Y. Sept. 21, 2022) ("This second guessing a clinical trial's design and enrollment criteria is not permitted under securities law."); *Pitman v. Immunovant*; No. 21-cv-918 (KAM)(VMS), 2024 WL 1342737, at *5 (E.D.N.Y. Mar. 29, 2024) (holding that plaintiffs' allegations "that, given the extent of the methodological flaws, defendants' statements regarding the results were actionable misstatements or half truths . . . fail as a matter of

law"); *Davison v. Ventrus Biosciences, Inc.*, No. 13-cv-3119 RMB, 2014 WL 1805242, at *8 (S.D.N.Y. May 5, 2014) (dismissing securities-fraud claims where plaintiffs merely "criticize[d] the study's methodology as unreliable"). "Securities law is simply not a vehicle through which courts will police disagreements in the cancer research community or the parameters of clinical trials." *Zagami v. Cellceutix Corp.*, No. 15-cv-7194 (KPF), 2016 WL 3199531, at *13 (S.D.N.Y. June 8, 2016). Plaintiff alleges no more than such disagreements here.

The AC's theory of fraud is that LUNAR's trial design had become obsolete by the time it was completed. The AC does not blame LUNAR's stewards for enrolling, at the outset, a patient population that mostly received ICIs in the second line, AC ¶ 66, or for not measuring more PD-L1 scores at baseline, *id.* ¶ 64, because when LUNAR was initiated in 2017, those decisions were not out of step with the alleged current standards of care, *see* AC ¶¶ 48, 51. The AC alleges, instead, that by the time the LUNAR trial was completed in November 2022, the standard of care for treating NSCLC patients had so "rapidly shifted" that LUNAR's "purportedly favorable results" were rendered "unreliable, uninterpretable, and essentially meaningless." *Id.* ¶¶ 50, 58. In the AC's words, "[w]hile the LUNAR trial was designed to evaluate TTFields as a second-line therapy in combination with either ICIs or docetaxel, during the course of the trial, the standard of care for NSCLC shifted to the use of ICIs as a first-line therapy[,] either alone, or in combination with chemotherapy." *Id.* ¶ 48. And the newfound "prevalen[ce]" of ICIs "meant that it was critical for the LUNAR trial's four subgroups to contain patient populations that were relatively balanced with respect to patients' PD-L1 scores." *Id.* ¶ 51.

The basis of the AC's claims, therefore, is that design choices that were explicable when LUNAR was initiated in 2017, *id.* ¶¶ 44, 48, had become "serious flaws" by the time it was completed, *id.* ¶¶ 6, 58, 133. The AC alleges that Defendants' statements were materially misleading because they "failed to disclose" these "serious flaws." *E.g.*, *id.* ¶¶ 58–72, 75. Three flaws, in

particular, are the basis for Plaintiff's claims. First, LUNAR only measured the PD-L1 scores of 55% of its trial population. *Id.* ¶¶ 9, 64. One consequence of this alleged flaw was that LUNAR's patients "were not stratified to ensure that PD-L1 status was not balanced among the trial's four subgroups." *Id.* ¶ 59 & n.4. Second, "98% of patients in LUNAR's ICI cohort had received ICIs for the first time as a second-line therapy during the trial." *E.g.*, *id.* ¶¶ 75(b); *see also id.* ¶¶ 65–66. The AC alleges that this undermined the usefulness of LUNAR's results because the survival benefit for patients treated with TTFields-plus-ICIs "was likely due to [those] patients benefiting" from receiving ICIs for the first time rather than receiving TTFields. *E.g.*, *id.* ¶¶ 75(b).[14] And third, 70% of LUNAR patients across both cohorts did not "fit the current first-line and second-line standards of care for NSCLC patients," and those that did fit the current standards of care fell mostly into the docetaxel arm of the trial, which "did not show a statistically significant overall survival benefit." *E.g.*, *id.* ¶¶ 75(c); *see also id.* ¶¶ 67–68. The AC alleges, accordingly, that "[t]he LUNAR trial did not incorporate the evolving standard of care for second-line treatment of NSCLC." *Id.* ¶ 93(c).

The AC's allegations as to why the omission of LUNAR's flaws was misleading make clear that Plaintiff's "real complaint" is with the design of the LUNAR trial. *Kleinman*, 706 F.3d at 154 (dismissing securities-fraud claim where plaintiff's "real complaint" was "that Defendants were able to tout positive results [from a clinical trial] only because they deviated from the established protocol . . . and changed the metrics by which data was analyzed"). The AC alleges that Defendants' choice not to collect PD-L1 scores for 45% of LUNAR's trial patients, and their corresponding choice not to "stratif[y] [LUNAR's patients] to ensure that PD-L1 status was balanced among the trial's four subgroups," "meant that NovoCure could never show that the trial results were not skewed by

[14] The AC alleges that the lifespan of patients who received TTFields-plus-ICIs was measured against the lifespan of patients who received ICIs alone. AC ¶ 110. The AC provides no allegations explaining why patients who received TTFields and ICIs would receive a benefit from receiving ICIs for the first time, but patients who received ICIs alone would not.

imbalances in patients' PD-L1 scores." *E.g.*, AC ¶ 75(a) (emphasis omitted). That is merely an allegation that LUNAR should have been designed to ensure that there were no imbalances in patients' PD-L1 scores. *See Pitman v. Immunovant, Inc.*, No. 21-cv-918 (KAM)(VMS), 2024 WL 964258, at *6 (E.D.N.Y. Feb. 25, 2024), *report and recommendation adopted*, *Pitman*, 2024 WL 1342737 (dismissing securities-fraud claims that amounted to allegations that clinical trial "should have been designed differently"). It is a criticism that LUNAR was not designed to do so. *See Fernandes v. Centessa Pharms. PLC*, No. 1:22-cv-8805 (GHW), 2024 WL 3638254, at *18 (S.D.N.Y. Aug. 2, 2024) (dismissing securities-fraud claims predicated on "critiques [that] merely disagree with the underlying studies' designs"); *see* AC ¶ 75(d) (alleging that "[a]s a result of" its failure to collect sufficient PD-L1 scores, "the LUNAR trial's results were unreliable, uninterpretable, and clinically meaningless").

The AC makes similar unactionable criticisms of LUNAR's patient-enrollment criteria. *Cachia*, 2022 WL 4367444, at *5 ("[S]econd guessing a clinical trial's design and enrollment criteria is not permitted under securities law."). The AC alleges that because 98% of patients in LUNAR's ICI cohort received ICIs for the first time in their second line of treatment, the purported success of LUNAR's ICI arm "was likely due to these patients benefiting from the ICIs" rather than TTFields, and that "the magnitude of the benefit" was likely due to an imbalance in patients' PD-L1 scores. *E.g.*, *id.* ¶ 75(b). And it alleges that because only 30% of LUNAR's patients received the current standard of care in their first and second lines of treatment, LUNAR's results did not show a "credibl[e]" survival benefit "in any currently[] relevant NSCLC patient population." *E.g.*, *id.* ¶ 75(c); *see also id.* ¶ 75(b) (alleging that these "explanation[s] are all the more likely because the trial's docetaxel cohort did not show a statistically significant improvement in overall survival with the addition of TTFields therapy"). Again, these are allegations that Defendants should have designed LUNAR differently, to enroll a patient population with a higher percentage of first-line treatment with ICIs. *See Pitman*, 2024 WL 964258, at *6; *Cachia*, 2022 WL 4367444, at *5,

Because the AC merely alleges criticisms of LUNAR's trial design, its fails to state a claim under Section 10(b). "The Second Circuit has emphasized that in scrutinizing a section 10(b) claim, a court does not judge the methodology of a [clinical] trial, but whether a defendant's statements about that study were false and misleading." *Abely*, 2013 WL 2399869, at *7 (citing *Kleinman*, 706 F.3d at 154–55). In *Kleinman*, the Second Circuit addressed securities-fraud claims based on statements touting a clinical trial's positive topline results. 706 F.3d at 153. The defendants disclosed that their trial had used a post-hoc analysis, but did not disclose that the post-hoc analysis was "curvilinear," and that curvilinear analysis "deviated from the established protocol." *Id.* at 154. The Second Circuit held these statements to be unactionable. It observed that the plaintiff's "real complaint [was] that Defendants were able to tout positive results only because they deviated from the established protocol . . . and changed the metrics by which data was analyzed," and explained that it was not the court's job "to evaluate the use of post-hoc analysis generally in the scientific community." *Id.* at 154–55. The defendants had "simply stated that a post-hoc analysis was used without specifying the methodology," and "nothing about this [was] misleading." *Id.* at 154. Moreover, it was "understood" that results from post-hoc analyses were "less significant," and therefore the defendants' statements "should . . . have [had] less impact on investors." *Id.*

Here, as in *Kleinman*, "Defendants stated that [LUNAR] showed positive results without stating the methodology." *In re Neurotrope, Inc. Sec. Litig.*, 315 F. Supp. 3d 721, 731 (S.D.N.Y. 2018) (citing *Kleinman*, 706 F.3d at 154). Plaintiff does not dispute that Defendants accurately disclosed LUNAR's topline results. *E.g.*, Opp. at 15 (conceding that "Defendants could have . . . simply stated that the trial had met its primary endpoint of a statistically significant improvement in overall survival with the addition of TTFields"). Instead, Plaintiff's complaint is that Defendants described LUNAR's results in positive terms—"clinically meaningful," "profound," "groundbreaking," etc.—based on a trial whose design and methodology he disputes. *See Kleinman*, 706 F.3d at 154. But "[i]t

is not the Court's job" to determine whether the flaws Plaintiff alleges with the LUNAR trial were "so anomalous" that stating the topline results of their trial was "fraudulent if [those methodologies were] not disclosed." *In re Neurotrope*, 315 F. Supp. 3d at 731. The AC provides no basis to conclude that Defendants were required to design the LUNAR trial in accordance with Plaintiff's view, or that Defendants' interpretations of LUNAR's results were irrational or unreasonable. *See id.* (dismissing securities-fraud claim alleging that trial used improper p-value because "Defendants have not cited to any FDA guidance or requirement that Defendants use a particular p-value in its Phase 2 clinical trials"); *see also Tongue*, 816 F.3d at 214 (dismissing securities-fraud claim alleging that defendants' interpretation of clinical trial's results misleadingly omitted contrary facts because plaintiffs did not "allege that Defendants' interpretation of the data was irrational or unreasonable"); *In Re Philip Morris*, 89 F.4th at 422 (analyzing authorities to assess whether defendants' statements were adequately pleaded to be unreasonable and thus misleading). Its criticisms of LUNAR's design are therefore unactionable. *See Zagami*, 2016 WL 3199531, at *13 ("Securities law is simply not a vehicle through which courts will police disagreements in the cancer research community or the parameters of clinical trials.").

The AC's further allegations that LUNAR was flawed as a commercial matter, rather than just as a matter of science, *see* AC ¶¶ 51, 70, 71, are also unactionable. One important consequence of LUNAR's methodological flaws, according to the AC, was that LUNAR's results would not drive immediate industry or commercial uptake of TTFields therapy. *See, e.g.*, *id.* ¶¶ 70 (alleging that "as a result of the LUNAR trial's significant issues, [TTFields] would not be widely adopted by the medical community until NovoCure was able to complete additional . . . trials"), 71 (alleging that the "prospect" of adoption of TTFields by the medical community "was years away" after the announcement of LUNAR's results, "and so were the potential revenues from expanding TTFields therapy to NSCLC patients"). The AC alleges that "in order for the LUNAR trial to reflect current

clinical practice—such that doctors were likely to consider TTFields as a second-line therapy if LUNAR was a success—the trial would need to enroll a patient population with a high rate of first-line therapy," and "it was critical for the LUNAR trial's four subgroups to contain patient populations that were relatively balanced with respect to patients' PD-L1 scores." AC ¶ 51 (emphasis added). Because LUNAR was not designed to do so, TTFields therapy "would not be widely adopted by the medical community until NovoCure was able to complete additional trials." Opp. at 35.

Defendants' positive statements about LUNAR's trial results, however, are not alleged to be statements about the "commercial success" of the LUNAR trial. Opp. at 3. Defendants stated that LUNAR's results were "clinically meaningful," "profound," "groundbreaking," and a "key finding." Those were not statements that LUNAR was the final step to industry or commercial uptake, and Defendants' statements elsewhere in the Class Period disavowed that notion. *See, e.g.*, AC ¶ 90 (Danziger stating at a February 23, 2023 press conference that "LUNAR is the *first of four pivotal studies* we expect to read out in the next two years which *could* dramatically increase the number of patients eligible for [TTFields]" (emphases added)). Industry uptake may be the ultimate goal, but reasonable investors understand that a trial can be "consider[ed] . . . a success" merely by demonstrating a step in that direction. AC ¶ 51. Reasonable investors "take into account the customs and practices of the relevant industry," *Omnicare*, 575 U.S. at 190, and scientists for hundreds of years have acknowledged that their breakthroughs stand on prior progress. *See* Letter from Isaac Newton to Robert Hooke, Feb. 5, 1675 ("If I have seen further it is by standing on the shoulders of giants.").[15] No reasonable investor, in context, would conclude from Defendants'

[15] It is not inaccurate to describe the results of one scientific study as meaningful simply because more work is required. In science, answers often lead to questions.

statements that industry uptake of TTFields would follow directly from the announcement of LUNAR's results. *See Omnicare*, 575 U.S. at 187.

Finally, the Court rejects, as other courts have, Plaintiff's argument that his claims are not predicated on "the LUNAR trial's serious flaws" themselves, AC ¶¶ 6, 58, 133, but on the fact that Defendants would never be able to "answer . . . question[s]" about those serious flaws "absent a new trial," Opp. at 32. *See Pitman*, 2024 WL 1342737, at *5 ("Plaintiff's attempt to distinguish between Plaintiff's opposition to the design of the clinical trials, and Plaintiff's opposition to the statements Defendants made about the clinical trial because of Plaintiff's opposition to the trial design, is not supported by the law."). Plaintiff's argument only confirms that his criticisms are with the design of the LUNAR trial, because it concedes that the answer to his criticism was "a new trial," Opp. at 32, and in particular, one that was designed in accordance with his critiques, *see id.* at 2 (arguing that "NovoCure would never be able to alleviate concerns that imbalances in patients' PD-L1 scores . . . had thrown off the LUNAR results[] *absent a new trial that collected PD-L1 data*" (emphasis added)).

In sum, Defendants' positive descriptions on LUNAR's trial results are not alleged to be actionable because Plaintiff's allegations as to their falsity allege no more than a criticism of LUNAR's design. *See, e.g.*, *In re Keryx Biopharmaceutica*ls, 2014 WL 585658, at *10 (dismissing securities-fraud claims whose "allegations as to falsity amount[ed] to a desire to have known aspects of [a trial's] methodology . . . earlier than such details were fully disclosed"); *Abely*, 2013 WL 2399869, at *8 (dismissing securities-fraud claims because the "plaintiff's allegations amount[ed] to a non-actionable critique of defendants' study design").

ii. Statement that "We Believe Our Protocol Incorporates the Evolving Standard of Care for Second-Line Treatment of NSCLC"

Defendants' statement in NovoCure's December 31, 2022 Form 10-K that "[w]e believe our protocol [for the LUNAR trial] incorporates the evolving standard of care for second-line treatment

of NSCLC," AC ¶ 92 (alterations in original), is also a non-actionable attack on LUNAR's trial design. NovoCure's Form 10-K stated, in relevant part:

> We believe our protocol [for the LUNAR trial] incorporates the evolving standard of care for second-line treatment of NSCLC. TTFields is intended principally for use in combination with other standard-of-care treatments, and LUNAR was designed to generate data that contemplates multiple outcomes, all of which we believe will be clinically meaningful.

Id. (alterations in original). The AC's allegations as to why this statement is misleading merely introduce a "dispute about [Defendants'] interpretation of [LUNAR's] data." *Tongue*, 816 F.3d at 214 (holding that such disputes are not actionable). On one hand, Defendants stated that they believed LUNAR's "protocol incorporates the evolving standard of care for second-line treatment of NSCLC," *id.*, and on the other hand, Plaintiff alleges that LUNAR's protocol did not, *id.* ¶ 93(c) (alleging that "[t]he LUNAR trial did not 'incorporate[] the evolving standard of care for second-line treatment of NSCLC" and that "'LUNAR was' not 'designed to generate data that contemplates multiple outcomes, all of which' would be 'clinically meaningful'").

Plaintiff's "competing . . . interpretation" of LUNAR's results is unactionable because he fails to adequately allege that "that Defendants' interpretation of the data was irrational or unreasonable." *Tongue*, 816 F.3d at 214; *accord In Re Philip Morris*, 89 F.4th at 420 ("[W]here plaintiffs (and others) take issue with a defendant's view regarding the results of the defendant's scientific studies but the defendant's competing analysis or interpretation of data is itself reasonable, there is no false statement." (quotations and alterations omitted)). The AC merely alleges that Defendants' statement was misleading because it "failed to disclose" the same three flaws with LUNAR's trial design that are detailed above, *id.* ¶ 93, namely, that "PD-L1 scores were missing for 45% of the patients in the LUNAR trial," *id.* ¶ 93(a), that "98% of patients in LUNAR's ICI cohort had received ICIs for the first time as a second-line therapy during the trial," *id.* ¶ 93(b), and that "only 30% of patients in the trial fit the current first-line and second-line standards of care for NSCLC patients,"

id. ¶ 93(c). As discussed, those allegations are no more than criticisms of LUNAR's trial design. They provide "no basis" for the Court to conclude that Defendants' interpretation of LUNAR's results was "unreasonable," *Kleinman*, 706 F.3d at 154; *Fernandes*, 2024 WL 3638254, at *20 (same), and accordingly, they fail to adequately allege that Defendants' statement was misleading, *see Cachia*, 2022 WL 4367444, at *5 ("[S]econd guessing a clinical trial's design . . . is not permitted under securities law.").

iii. Statement that Defendants "Would Expect to Address All the Issues" at the June Conference

The AC also alleges, unsuccessfully, that Doyle's statement during the Class Period that "we would expect to address all the issues with respect to balance and PD-L1 status" at the June ASCO conference, AC ¶ 108, was misleading because it omitted the first two "serious flaws" with LUNAR's methodology discussed above, *id.* ¶ 58. On May 4, 2023 conference call, an analyst asked Doyle:

> And then just a question on the LUNAR presentation. Some of the questions are unknowns or related to PD-L1 status, clearly, whether you have data on PD-L1 status for a large percentage of the patients, whether there was an imbalance, do you expect that the [June] presentation will address these questions such that there won't be ambiguity about the results for the [ICI] groups following ASCO[?]

Id. ¶ 108. Doyle responded:

> So first and foremost, we're looking forward to seeing everybody in June. Following the presentation, we will also have an investor meeting that will include KOLs, investigators as well as NovoCure personnel. And we would expect to address all the issues with respect to balance and PD-L1 status at that time.

Id.

Doyle's response, as alleged, did not misleadingly omit the alleged flaws in LUNAR's trial design. The AC alleges that Doyle's response "failed to disclose" that "PD-L1 scores were missing for 45% of the patients in the LUNAR trial," and that "98% of patients in LUNAR's ICI cohort had received ICIs for the first time as a second-line therapy during the trial," *id.* ¶ 109. It articulates the

same non-actionable critiques of LUNAR's trial design in support of these allegations, *see id.* ¶¶ 109(a) (alleging that "missing" PD-L1 scores "meant that NovoCure could never show that the trial results were not skewed by imbalances in patients' PD-L1 scores" (emphasis omitted)), 109(b) (alleging that "[s]ince 98% of patients in LUNAR's ICI cohort" only received ICIs in their second line of treatment, the success of the LUNAR's ICI arm "was likely due to these patients benefiting from the ICIs"), and alleges that, because of these design flaws, "the presentation of the LUNAR data" at the June press conference "could not," as Doyle stated, "'address all the issues with respect to balance and PD-L1 status.'" *Id.* ¶ 109(a); *see also id.* ¶ 109(b) (alleging that "given that PD-L1 scores were missing for nearly half of patients[,] there would continue to be," as the analyst suggested, "ambiguity about the results for the [ICI] groups" (alteration in original)).

In addition to its non-actionable criticisms of LUNAR's trial design, the AC fails to allege any conflict between Doyle's statement and the omitted facts. To adequately plead a materially misleading omission, "the omitted facts must 'conflict with what a reasonable investor would take from the statement itself.'" *Tongue*, 816 F.3d at 211 (quoting *Omnicare*, 757 U.S. at 189). Plaintiff argues that the omitted flaws with LUNAR conflict with Doyle's statement because Doyle's statement "indicat[ed] that NovoCure had enough data to address" the analyst's "concerns about whether PD-L1 imbalances had impacted LUNAR's results," Opp. at 18, even though LUNAR had not collected PD-L1 scores for 45% of its patients, *id.*; *see also* AC ¶ 109(a). No reasonable investor, however, would understand Doyle's statement as a promise that "NovoCure had enough data" to assuage the analyst's concerns. Opp. at 18. Doyle did not say that the June presentation would show that LUNAR "had enough data," and he did not say that the June presentation would "address" the analyst's concerns to the analyst's satisfaction. *Id.* He stated merely that the June presentation would "address" the issues the analyst raised. AC ¶ 108. No reasonable investor

would interpret this statement a suggestion that LUNAR had collected PD-L1 scores from all, or "enough," of its patient population. Opp. at 18.

iv. Statements that LUNAR's "Patient Enrollment" and "Trial Arms" Were "Well Balanced"

Defendants' statements that LUNAR's "patient enrollment" and "trial arms" were "well balanced," AC ¶¶ 73, 84, 92, 99, are also not plausibly alleged to be misleading. In two SEC filings published during the Class Period, Defendants stated, in relevant part, that "Patient enrollment [in the LUNAR study] was well balanced between the ICI and docetaxel cohorts of the experimental and control arms." *Id.* ¶¶ 73, 92. And later, during a February 23, 2023 "conference call with analysts and investors," an analyst asked Doyle: "Can you talk about your confidence level that the active and control arms in the study are balanced in terms of patient characteristics and first-line therapy?" *Id.* ¶ 99. Doyle responded, in full:

> Sure. So—to remind everyone, this is a randomized study. And we've said that the control groups behaved as expected and that the arms were well balanced in terms of numbers. And we look forward to sharing all the details with you, as I said, later in the summer. But all the indications, as we announced in the press release show balance. And as I said, I'll just say it again, appropriate and expected results in the control arm.

Id.; Brody Decl., Ex. 6.[16] The AC alleges that each of these statements was misleading because they "failed to disclose" that "PD-L1 scores were missing for 45% of the patients in the LUNAR trial." AC ¶¶ 73, 92, 99. The AC accepts that LUNAR's patient enrollment and trial arms were "well balanced in terms of the number of patients," *id.* ¶ 100 (quotations and alterations omitted); *see also id.* ¶¶ 75(a) (alleging that "patient enrollment numbers may have been well balanced between the immune checkpoint inhibitor and docetaxel cohorts of the experimental and control arms" (quotations and alterations omitted)), 93(a) (same), but alleges that because LUNAR did not collect

[16] Plaintiff only alleges that Doyle's statements regarding "balance" were misleading. Dkt. No. 70-1 at 16. The remainder of Doyle's response is provided for context.

PD-L1 scores for 45% of its patients, and because LUNAR's patients were not stratified according to their PD-L1 scores, Defendants "could not tell whether [that] key patient characteristic . . . was well-balanced between the trial arms," and likewise "could not tell whether 'all the indications showed balance'" along that key characteristic. Opp. at 18 (quoting AC ¶¶ 75, 84, 93, 100).

As an initial matter, Defendants' statements that LUNAR's enrollment and trial arms were "well balanced" were statements of opinion interpreting the LUNAR trial data.[17] "[W]ell balanced" is an "inherently subjective" term whose "objective truth or falsity," at least as alleged, cannot "be ascertained with certainty." *Buhrke Fam. Revocable Tr. v. U.S. Bancorp*, 726 F. Supp. 3d 315, 346 (S.D.N.Y. 2024) (quoting *In Re Philip Morris*, 89 F.4th at 418). The AC does not allege that "well balanced" has a more definite meaning in the context of this case. Without such allegations, there is no "black-and-white standard by which to verify whether" the LUNAR data was in fact "well balanced." *In Re Philip Morris*, 89 F.4th at 418. Defendants' statements were therefore statements of opinion, *see id.* at 418–19 (holding that statements that clinical trials were "conducted according to Good Clinical Practice" guidelines were statements of opinion), and Plaintiffs do not dispute that they interpret the "balance" in LUNAR's data, *see* Opp. at 32–33.

The AC fails to adequately allege that Defendants' statements were misleading because it fails to allege more than "a dispute about the proper interpretation of data." *Tongue*, 816 F.3d at 214. In *Tongue*, as in this case, the plaintiffs alleged that a company had misleadingly stated positive interpretations of a clinical trial's results while omitting contrary facts about the trial's methodology. *Id.* at 213–14. In particular, the defendants omitted that the FDA had repeatedly criticized the methodology of the clinical trial. *Id.* at 212. The FDA ultimately rejected the company's application

[17] Plaintiff's brief states, in an unelaborated footnote, that Defendants' descriptions of LUNAR's enrollment and trial arms as "well balanced" were statements of fact rather than opinion. Opp. at 21–22 n.9. But the remainder of Plaintiff's brief defends the statements as opinion statements, not fact statements. *See id.* at 21–26.

for approval for use in the field based on its methodological concerns, *id.* at 207, though it later accepted the company's application after resubmission, *id.* at 207, 214. The Second Circuit held that the "Defendants' statements were not misleading simply because the FDA disagreed with Defendants' interpretation of the data; an issuer is not liable merely because it 'knows, but fails to disclose, some fact cutting the other way.'" *Id.* at 214 (quoting *Omnicare*, 575 U.S. at 189). The court explained that the "Defendants' statements about the effectiveness of [the drug] cannot be misleading merely because the FDA disagreed with the conclusion—so long as Defendants conducted a 'meaningful' inquiry and in fact held that view, the statements did not mislead in a manner that is actionable." *Id.* at 214 (quoting *Omnicare*, 575 U.S. at 188). That accorded with the Supreme Court's guidance on misleading opinion statements in *Omnicare*, which explained that when "an issuer tell investors that 'We believe our conduct is lawful,'" that statement "does not imply that the issuer's conduct is, in fact, lawful, but only that the issuer has conducted a meaningful inquiry and has a reasonable basis upon which to make such an assertion." *Id.* (quoting *Omnicare*, 575 U.S. at 188). The plaintiffs in *Tongue* had not alleged that the basis for "Defendants' interpretation of the data was irrational or unreasonable," and accordingly, they had alleged "little more" than a non-actionable "dispute about the proper interpretation of data." *Id.* at 214.

Here, the AC alleges that LUNAR would have needed to collect more than 55% of its patients' PD-L1 scores before Defendants could interpret its trial arms to be "well balanced," *see, e.g.*, AC ¶ 75(a), but it fails to allege that Defendants' contrary "interpretation of the data"—*i.e.*, that 55% sufficed—"was irrational or unreasonable." *Tongue*, 706 F.3d at 214. The AC does not allege that PD-L1 scores were not well balanced across LUNAR's trial arms, *see, e.g.*, Opp. at 32 (conceding that "Plaintiff's claim is not that the LUNAR results were skewed by patients responding differently to ICIs based on their PD-L1 scores"), only that Defendants "could not tell whether [the arms] were well balanced" because 55% was an insufficient amount of data on which to base this claim, *e.g.*, AC

¶ 93(a). But the allegations in the AC, and the materials incorporated within or integral to it, provide "no basis to believe" that Defendants' "competing . . . interpretation" was "unreasonable." *Kleinman*, 706 F.3d at 154; *accord, e.g.*, *Fernandes*, 2024 WL 3638254, at *20 (same).

To the contrary, on the materials before the Court, "Defendants' statements appear to be supported by [a] 'meaningful inquiry'" into the balance of LUNAR's patient characteristics. *In re Philip Morris Int'l Inc. Sec. Litig.*, 437 F. Supp. 3d 329, 353 (S.D.N.Y. 2020), *aff'd sub nom. In Re Philip Morris*, 89 F.4th 408; (quoting *Tongue*, 816 F.3d at 214). The PowerPoint presentation Defendants used in their corrective disclosure at the June 6, 2023 ASCO conference, *see* AC ¶¶ 113–14, presented data on LUNAR's patients' PD-L1 scores and showed that, for the 55% of patients whose PD-L1 scores were recorded, the proportions with low, medium, and high PD-L1 scores differed by no more than 6% across each of LUNAR's experimental and control arms. Brody Decl., Ex. 12 at 9.[18] And NovoCure's Form 8-K filed on the same day, AC ¶ 110, attached slides that presented data on the PD-L1 scores in each of LUNAR's four trial arms and showed disparities of no more than 6% in the ICI cohort and 7% in the docetaxel arm where PD-L1 scores were collected. Brody Decl., Ex. 10 at 16.[19] The AC affirmatively alleges that the data Defendants revealed in their corrective disclosures was truthful. *E.g.*, AC ¶¶ 110–116 (detailing Defendants' corrective disclosures and alleging that "the truth [was] revealed"). And it provides no basis to conclude that the 6% and 7% disparities across LUNAR's experimental and control arms would not "indicat[e] . . . balance," *id.* ¶ 99, nor that 55% was an insufficient proportion of LUNAR's randomized patient population from which to draw a conclusion about the balance of characteristics across its trial arms. In the absence of such allegations, there is "no basis" to conclude that Defendants' interpretation

[18] This presentation is integral to the AC because the AC relies heavily upon its terms and effect. *Supra* Part III.
[19] The AC incorporates this filing by reference because it quotes from the filing extensively in alleging Defendants' corrective disclosure. *Supra* Part III.

that LUNAR's trial arms were "well balanced" is "unreasonable." *Kleinman*, 706 F.3d at 154–55; *see also In re Neurotrope*, 315 F. Supp. at 732 (dismissing securities-fraud claims because plaintiffs' allegations merely alleged that defendants' choice of p-value in a clinical trial was "so anomalous that the resulting statistical modeling is fraudulent if the p-value is not disclosed," explaining that "[i]t is not the Court's job to determine an appropriate p-value for pharmaceutical studies").

Moreover, the AC does not adequately allege that Defendants' interpretations of LUNAR's trial arms as "well balanced" did not "fairly align with the information in [their] possession at the time." *Omnicare*, 575 U.S. at 189. "Defendants [are] only tasked with making statements that fairly align[] with the information [they currently] possess," *Tongue*, 816 F.3d at 212 (quotation omitted), and their omissions are only actionable if the omissions "*substantially undermine* the conclusion that a *reasonable investor* would reach from [their] statement[s]," *In Re Philip Morris*, 89 F.4th at 423 (emphases in original, other alterations and quotations omitted). As alleged, the fact that Defendants' statements were based on a data set that included 55% of PD-L1 scores, rather than some higher percentage, is at most "a fact that would have potentially undermined Defendants' [interpretation]." *Tongue*, 706 F.3d at 212. LUNAR's patients were randomized into their respective trial arms, AC ¶ 45, and the 55% of patients for whom PD-L1 scores were collected are not alleged to have shown any imbalance along that characteristic, *see, e.g.*, Opp. at 32 ("Plaintiff's claim is not that the LUNAR results were skewed by patients . . . based on their PD-L1 scores."). Having failed to adequately allege that Defendants' interpretations of LUNAR's data did not "fairly align with the information in [their] possession," the AC fails to allege that Defendants' omissions were misleading "merely because [the omissions] tended to cut against their [statements]." *Tongue*, 816 F.3d at 212.

For these reasons, the AC fails to adequately plead that Defendants' interpretations of the "balance" of patient characteristics in LUNAR's trial arms were "unreasonable," *Kleinman*, 706 F.3d at 154, and also fails to adequately plead that Defendants' interpretations were "substantially

undermined by their failure to disclose" that LUNAR did not collect 45% of its patients' PD-L1 scores, *In Re Philip Morris*, 89 F.4th at 423 (quotations and alterations omitted). Both require dismissal of his claims under Section 10(b). The Court will not otherwise weigh in on whether Plaintiff's or Defendants' interpretation of LUNAR's data is proper. *See Zagami*, 2016 WL 3199531, at *13 ("Securities law is simply not a vehicle through which courts will police disagreements in the cancer research community or the parameters of clinical trials."); *Kleinman*, 706 F.3d at 154–55 ("Our job is not to evaluate the use of post-hoc analysis generally in the scientific community . . . [i]nstead, we look to see whether the statements made were misleading or rendered misleading due to an omission").

v. Statement at the January 10, 2023 Conference

The AC fails to allege that Doyle's response to an analyst's question about LUNAR's PD-L1 scores was materially misleading because, again, its allegations as to why the response was misleading merely dispute Doyle's interpretation of LUNAR's data. *See, e.g.*, *In Re Philip Morris*, 89 F.4th at 420 ("We have rejected the proposition that a mere dispute about the proper interpretation of data can form a basis for liability under section 10(b) and Rule 10b-5."). During a January 10, 2023 healthcare conference, an analyst allegedly asked Doyle: "So it's my understanding, the LUNAR study was started before PD-L1 status at baseline was I guess, a thing. Is that correct? And if it's so, did you guys measure PD-[L]1 status at baseline?" AC ¶ 84; Brody Decl., Ex. 3. Doyle responded:

> So the answer to your questions, and I know why you asked this, right? There was a short note yesterday about PD-[L]1 status. So the first thing I'll remind you, this is a trial in the second line, not the first line. And PD-[L]1 status has not shown any relevance in second line.
>
> Secondly, I will tell you that when we—and I didn't mention this in the presentation. But there was nothing unusual about the control group. So when you report top line data, it's very encouraging to hear that the trial was successful in the top line. But then you have to ask what about the controls. Was there anything funky about the controls. So these arms were well balanced and the controls behaved as expected, in line with prior studies. So there was nothing funky here. So this is a well-powered, randomized

> study where we showed a profound benefit. And the full data, including PD-[L]1 status will be presented later. But I think that's a red herring.

AC ¶ 84; Brody Decl., Ex. 3. The AC first alleges that Doyle's statements that LUNAR "showed a profound benefit" and that its "arms were well balanced" were misleading. The AC alleges, again, that these statements were misleading because Doyle omitted that LUNAR only collected PD-L1 scores for 55% of its patient population and thus "could not tell" whether "the trial results were not skewed by imbalances in patients' PD-L1 scores." *Id.* ¶¶ 85, 86. For the same reasons discussed above, those allegations are non-actionable criticisms of LUNAR's trial design. In alleging that it was misleading for Doyle to describe LUNAR's results as "profound" without stating that LUNAR had only collected 55% of its patients' PD-L1 scores, the AC merely alleges that Defendants "stated that [LUNAR] showed positive results without stating the methodology." *In re Neurotrope*, 315 F. Supp. at 731; *accord Kleinman*, 706 F.3d at 154 ("The press release simply stated that a post-hoc analysis was used without specifying the methodology; nothing about this is misleading."). And in alleging that it was misleading for Doyle to state that LUNAR's "arms were well balanced" without stating that LUNAR had only collected 55% of its patients' PD-L1 scores, the AC merely alleges "a dispute about the proper interpretation of data," namely, whether 55% is enough data to conclude that a trial's arms are well balanced. *Tongue*, 816 F.3d at 214; *see also In Re Philip Morris*, 89 F.4th at 420 ("We have rejected the proposition that a mere dispute about the proper interpretation of data can form a basis for liability." (quotations and alterations omitted)).

Nor was it misleading for Doyle to state that "the full data, including PD-[L]1 status will be presented later." AC ¶ 84. The AC alleges that this statement was misleading because "the full data . . . could not 'be presented later,'" as "PD-L1 scores were missing for 45% of patients in the trial." *Id.* ¶ 87 (quoting *id.* ¶ 84). No reasonable investor, however, would interpret Doyle's statement as implying that LUNAR had collected more than 55% of its PD-L1 scores. Doyle merely stated that

Defendants would present all of the data they had from the LUNAR trial at a later date, and the AC does not dispute that they did just that. *See, e.g. id.* ¶¶ 64–72 (alleging that "NovoCure released the LUNAR data on June 6, 2023" and detailing the alleged "response to the release of the full LUNAR data").

The AC also alleges that it was misleading for Doyle to respond that "PD-L1 status has not shown any relevance in the second line" and to "characterize patients' PD-L1 status as a 'red herring,'" *id.* ¶ 87, but its allegations as to why these statements were misleading, again, present a non-actionable "dispute about the proper interpretation of data." *Tongue*, 816 F.3d at 214. The AC alleges, at bottom, that PD-L1 scores "*were* . . . relevant" in the second line, and thus that it was misleading to say that they were not. AC ¶ 87 (emphasis added). It alleges that "the effectiveness of ICIs generally increases with higher PD-L1 scores, regardless of whether a patient is given ICIs [as] a first-line or second-line treatment," and that "PD-L1 scores were particularly relevant for the 69% of patients in the LUNAR trial who were receiving ICIs for the first time as a second-line therapy." *Id.*; *see also* Opp. at 29 ("[I]t makes little sense that PD-L1 scores would have no relevance for the ICI-naïve patients, who had only received chemotherapy as a first-line treatment.").

The AC's allegations that PD-L1 status was relevant to patients' second-line treatment do not adequately plead that Doyle's statements were misleading because they do not adequately plead that Doyle's contrary interpretation—that PD-L1 status "ha[d] not shown relevance"—was "objectively irrational or unreasonable." *In Re Philip Morris*, 89 F.4th at 422. As discussed, on the materials before the Court, Doyle's view that PD-L1 scores were "well balanced" across LUNAR's trial arms "appear[s] to be supported by [a] 'meaningful inquiry' into" LUNAR's data, *In re Philip Morris*, 437 F. Supp. at 353 (quoting *Tongue*, 816 F.3d at 214), and is not adequately alleged to be "substantially undermined" by the fact that LUNAR collected only 55% of its patients' PD-L1 scores, *In Re Philip Morris*, 89 F.4th at 423. *See generally supra* Part IV.B.1.b.iv. And Plaintiff's entire

theory as to why PD-L1 scores *were* relevant in the second line is that PD-L1 scores may have not been "well balanced,"[20] *see* AC ¶ 87, as that would permit LUNAR's results to be "skewed by patients responding differently to ICIs based on their PD-L1 scores," *id.* ¶ 7; *see also id.* ¶ 87 (alleging that PD-L1 status was relevant because "the effectiveness of ICIs generally increases with higher PD-L1 scores"). Doyle's statement that PD-L1 status "ha[d] not shown any relevance in the second line," therefore, appears supported by the same "meaningful inquiry" that supported his statements about the balance of LUNAR's patient characteristics, *see In re Philip Morris*, 437 F. Supp. at 353; *Tongue*, 816 F.3d at 214, and again is not substantially undermined by LUNAR's choice not to collect 45% of its patients' PD-L1 scores, *see In Re Philip Morris*, 8 F.4th at 423. Accordingly, the AC does not provide a "basis to believe that" Doyle's interpretation of the relevance of PD-L1 status to LUNAR's results was "unreasonable," and the AC's "competing . . . interpretation" is not actionable. *Kleinman*, 706 F.3d at 154; *see also In Re Philip Morris*, 8 F.4th at 423.

The AC further alleges that it was misleading for Doyle to respond that "there was nothing unusual about the control group" and that "there was nothing funky here," AC ¶ 86, but these allegations, too, merely dispute Doyle's interpretation of LUNAR's data. *Tongue*, 816 F.3d at 214.[21] The AC alleges that these statements were misleading because LUNAR had not collected enough PD-L1 scores for Doyle to be able to "tell . . . whether there was anything unusual about the PD-L1 scores of patients in the control group." *Id.* ¶ 86. In context, however, Doyle was talking about the "behav[ior]" of LUNAR's control groups, not their PD-L1 scores. *Id.* ¶ 84. Doyle did not mention

[20] Plaintiff also argues in his brief that Doyle's statement would have misled a reasonable investor into thinking that "there was no potential for patients' PD-L1 scores to impact the effectiveness of the ICIs they received during the trial." Opp. at 28. No reasonable investor would have drawn this conclusion from Doyle's statement. Doyle said that PD-L1 status had not "*shown* any relevance in the second line," not that PD-L1 status had no potential to be relevant in the second line. AC ¶ 87.

[21] These statements are also statements of opinion. Plaintiff contends, in the same unelaborated footnote discussed above, that Doyle's statement that "there was nothing unusual about the control group" was a statement of fact, though he treats this statement as one of opinion everywhere else in his brief. Opp. at 21 n.9. "Unusual" is an "inherently subjective" term. *Buhrke*, 726 F. Supp. 3d at 346. The AC alleges no "objective, black-and-white standard by which to verify" whether LUNAR's control arms "were in fact [unusual]." *In Re Philip Morris*, 89 F.4th at 418.

PD-L1 status when he opined about LUNAR's controls. He posed a question to himself—"[w]as there anything funky about the controls"—and then he answered that question by comparing the controls to the behavior of controls in "prior studies." *Id.* ("But then you have to ask what about the controls. Was there anything funky about the controls. So these arms were well balanced and the controls behaved as expected, in line with prior studies. So there was nothing funky here."). In context, no reasonable investor would interpret Doyle's statement as one about the PD-L1 scores in LUNAR's controls, rather than about the controls' behavior. *See Omnicare*, 575 U.S. at 190 (noting that "whether an omission makes an expression of opinion misleading always depends on context").

Nor did the posture of Doyle's statements "as a response to a specific question" about PD-L1 status render them misleading. Opp. at 27 (quoting *Abramson v. Newlink Genetics Corp.*, 965 F.3d 165, 178 (2d Cir. 2020)). Plaintiff argues that the particular questions the analyst asked, both of which related to PD-L1 scores, would lead a reasonable investor to conclude that Doyle's responses that LUNAR's "arms were well balanced" and that "there was nothing unusual about the control group" were directed to the balance and usualness of the arms' PD-L1 scores. *Id.* It is true that the analyst asked about PD-L1 scores, and specifically asked whether Defendants "measure[d] PD-L1 status at baseline." AC ¶ 84. But Doyle did not answer those questions. Instead, he fought the premise of the questions and contended that they were misguided. *See id.*; Brody Decl., Ex. 3 ("I know why you asked this, right? . . . I think that's a red herring."). No reasonable investor would interpret Doyle's combative response to those questions as an answer in the affirmative, *i.e.*, an answer confirming that LUNAR had "measured PD-L1 status at baseline." AC ¶ 84; *see Colbert v. Rio Tinto PLC*, 392 F. Supp. 3d 329, 339 (S.D.N.Y. 2019), *aff'd*, 824 F. App'x 5 (2d Cir. 2020) (rejecting argument that defendant's response to an investor's question was misleading "because [the defendant] was being asked about one specific option . . . but discussed other . . . options in his answer" (quotations and alterations omitted)).

Accordingly, Doyle's response, considered in context, is not adequately alleged to be misleading.

vi. Optimistic Statements Regarding the Future Impact of LUNAR's Trial Results

Finally, Defendants' "optimistic" statements regarding the future impact of LUNAR's trial results, Opp. at 34–35, were not misleading because they were non-actionable corporate puffery.[22] Defendants stated that the "successful LUNAR study marks the beginning of a transformational period," AC ¶ 78; *see also id.* ¶ 90 ("The positive top-line readout from the pivotal LUNAR study marked the beginning of a transformational 24 months for NovoCure."), that Defendants were "energized by the prospect of treating tens of thousands of patients who could benefit from [TTFields]," *id.* ¶ 78, that they were "now standing on the threshold of the opportunity to treat many, many more patients" and "excited that the promise to bring [TTFields] into new indications is here," *id.* ¶ 82, and that they "believe[d] the LUNAR data have the potential to transform the treatment paradigm for [NSCLC] patients," *id.* ¶ 94.

These are general statements of optimism or puffery both because they "lack the sort of definite positive projections that might require later correction," *Vivendi*, 838 F.3d at 245 (quotation omitted), and because they are exactly the kinds of "optimistic" and "confident" statements that "can be expected" of businesses and their managers, *Shields*, 25 F.3d at 1129–30. No reasonable investor would rely, for example, on the notion of a "transformational period," AC ¶ 78, or the mere "prospect," "potential," or "promise" of more use cases, *id.* ¶¶ 78, 82, 94, "as a guarantee of some

[22] Defendants also argue that these statements are non-actionable because they are protected by the PSLRA's safe harbor for forward-looking statements. Mem. at 34–35; *see* 15 U.S.C.A. § 78u-5. Because the statements are non-actionable puffery, the Court does not reach this argument. The Court notes that Defendants' briefing does not address the applicability the safe harbor to statements alleged to have omitted existing material information, rather than statements exclusively about the future. *See, e.g.*, *In re Complete Mgmt. Inc. Sec. Litig.*, 153 F. Supp. 2d 314, 340 (S.D.N.Y. 2001) (explaining that the PSLRA safe harbor applies "to forward-looking statements *only*, and not to material omissions or misstatements of historical fact"); *City of Providence v. Aeropostale, Inc.*, No. 11 CIV. 7132 CM THK, 2013 WL 1197755, at *12 (S.D.N.Y. Mar. 25, 2013) ("[T]he safe harbor does not apply to material omissions.") (collecting cases).

concrete fact or outcome." *City of Pontiac*, 752 F.3d at 185. Defendants' statements did no more than "place a positive spin on developments" regarding the LUNAR trial. *In re AstraZeneca plc Sec. Litig.*, No. 21-cv-722 (JPO), 2022 WL 4133258, at *8 (S.D.N.Y. Sept. 12, 2022), *aff'd sub nom. Nandkumar v. AstraZeneca PLC*, No. 22-2704-cv, 2023 WL 3477164 (2d Cir. May 16, 2023) (holding statements that defendant was "moving quickly but without cutting corners" and that Phase II/III clinical trial "remained 'on track'" were non-actionable puffery despite failures to disclose alleged "flaws in [trial] design") (quoting *In re EDAP TMS S.A. Sec. Litig.*, No. 14-cv-6069, 2015 WL 5326166, at *9 (S.D.N.Y. Sept. 14, 2015)) (collecting cases).

2. Scienter

a. Legal Standard

The AC also does not adequately plead scienter. Under the heightened pleading standards of Fed. R. Civ. P. 9(b) and the PSLRA, a plaintiff alleging securities fraud must allege "with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A); *see also Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 313 (2007). The question "is whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Tellabs*, 551 U.S. at 322–23.

"The requisite state of mind in a section 10(b) and Rule 10b–5 action is an intent 'to deceive, manipulate, or defraud.'" *ECA, Loc. 134 IBEW Joint Pension Tr. of Chicago v. JP Morgan Chase Co.*, 553 F.3d 187, 198 (2d Cir. 2009) (quoting *Tellabs*, 551 U.S. at 313). "In addition to intent, recklessness is a sufficiently culpable mental state for securities fraud in this circuit." *Id.* That standard can be satisfied "(a) by alleging facts to show that defendants had both motive and opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness." *Kalnit v. Eichler*, 264 F.3d 131, 138 (2d Cir. 2001) (internal quotation

marks and citation omitted). A plaintiff need not rely exclusively on one of these theories. "Where motive is not apparent, it is still possible to plead scienter by identifying circumstances indicating conscious behavior by the defendant, though the strength of the circumstantial allegations must be correspondingly greater." *Id.* (quoting *Beck v. Mfrs. Hanover Trust Co.*, 820 F.2d 46, 50 (2d Cir. 1987)).

Reckless conduct is "conduct which is highly unreasonable and which represents an extreme departure from the standards of ordinary care to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it." *In Re Carter-Wallace Sec. Litig.*, 220 F.3d 36, 39 (2d Cir. 2000) (internal quotation marks and citation omitted). A plaintiff alleging recklessness must allege "conscious recklessness—i.e., a state of mind approximating actual intent, and not merely a heightened form of negligence." *Stratte-McClure v. Morgan Stanley*, 776 F.3d 94, 106 (2d Cir. 2015) (internal quotation marks and citation omitted). "Securities fraud claims typically have sufficed to state a claim based on recklessness when they have specifically alleged defendants' knowledge of facts or access to information contradicting their public statements." *Kalnit*, 264 F.3d at 142 (internal quotation marks and citation omitted). "Under such circumstances, defendants knew or, more importantly, should have known that they were misrepresenting material facts related to the corporation." *Id.* (internal quotation marks and citation omitted).

An "inference of scienter must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs*, 551 U.S. at 314. If an inference of fraudulent intent is not "at least as compelling" as a contrary inference, it is inadequate, even in a "close case." *Slayton v. Am. Exp. Co.*, 604 F.3d 758, 777 (2d Cir. 2010). An inference of scienter need not be "irrefutable, i.e., of the 'smoking-gun' genre, or even the most plausible of competing inferences." *Tellabs*, 551 U.S. at 324 (quotation omitted); *see also City of Pontiac Gen. Employees' Ret. Sys. v. Lockheed Martin Corp.*, 875 F. Supp. 2d 359, 372 (S.D.N.Y. 2012) ("[A]t the motion to dismiss stage, a tie on scienter goes to the plaintiff."). "But generic and

conclusory allegations based upon rumor or conjecture are undisputedly insufficient to satisfy the heightened pleading standard." *Campo v. Sears Holdings Corp.*, 635 F. Supp. 2d 323, 336 (S.D.N.Y. 2009), *aff'd*, 371 F. App'x 212 (2d Cir. 2010). The ultimate "inquiry on a motion to dismiss is as follows: '[w]hen the allegations are accepted as true and taken collectively, would a reasonable person deem the inference of scienter at least as strong as any opposing inference?'" *In re Scot. Re Grp. Sec. Litig.*, 524 F. Supp. 2d 370, 383 (S.D.N.Y. 2007) (quoting *Tellabs*, 551 U.S. at 326).

b. Application

The AC fails to raise the requisite strong inference of scienter. The AC's scienter allegations track the two avenues for pleading scienter set forth in *Kalnit*: allegations that Defendants had a "motive to commit securities fraud," Opp. at 39 (quotation omitted); AC ¶¶ 135–42, and allegations that Defendants "knew and/or recklessly disregarded" "confidential proprietary information regarding NovoCure" and regarding "the problems with the LUNAR trial data throughout the Class Period," AC ¶¶ 127–34. The Court assesses these categories of allegations "holistically," "accepting the whole factual picture painted by the Complaint," *Slayton*, 604 F.3d at 775 (quotations omitted), and concludes that they do not give rise to an "inference of scienter at least as compelling as any opposing inference of nonfraudulent and nonreckless intent." *S. Cherry St., LLC v. Hennessee Grp. LLC*, 573 F.3d 98, 111 (2d Cir. 2009).

i. Motive

To start, Plaintiff's allegations do not raise a strong inference that Defendants possessed a motive to commit securities fraud.[23] Plaintiff relies on the AC's allegations of stock trades made by

[23] Motive allegations can satisfy the scienter element of a securities-fraud claim if and only if they are combined with sufficient allegations that defendants had "an opportunity to commit fraud." *Glickman v. Alexander & Alexander Servs., Inc.*, No. 93-cv-7594 (LAP), 1996 WL 88570, at *6 (S.D.N.Y. Feb. 29, 1996) ("To satisfy the scienter requirement by this method, both a motive and an opportunity to commit fraud must be pleaded."). Here, "[i]t is undisputed that as senior officers" at NovoCure, the individual defendants "had the opportunity to commit fraud." *In re Wachovia Equity Sec. Litig.*, 753 F. Supp. 2d 326, 349 (S.D.N.Y. 2011) (quotation omitted). Defendants also do not dispute that the individual defendants' alleged motive and opportunity to commit fraud could, if adequately pleaded, be imputed to NovoCure. *See*

the Individual Defendants, *see* AC ¶ 136, whose timing and amount he argues were "unusual and suspicious" because they were made during the Class Period before Defendants' corrective disclosures at the June presentation, Opp. at 39–40. "The Second Circuit has acknowledged that an inference of motive may arise where 'corporate insiders allegedly make a misrepresentation in order to sell their own shares at a profit,'" *In re Iconix Brand Grp., Inc.*, No. 15 CIV. 4860 (PGG), 2017 WL 4898228, at *15 (S.D.N.Y. Oct. 25, 2017) (quoting *ECA*, 553 F.3d at 198), if "those trades are suspicious in timing or amount," *In re Lululemon Sec. Litig.*, 14 F. Supp. 3d 553, 584 (S.D.N.Y. 2014), *aff'd*, 604 Fed. App'x 62 (2d Cir. 2015). "However, 'executive stock sales, standing alone, are insufficient to support a strong inference of fraudulent intent.'" *City of Coral Springs Police Officers' Ret. Plan v. Farfetch Ltd.*, 565 F. Supp. 3d 478, 486–87 (S.D.N.Y. 2021) (quoting *In re Bristol-Myers Squibb Sec. Litig.*, 312 F. Supp. 2d 549, 561 (S.D.N.Y. 2004)).

The "insider sales" alleged in the AC do not give rise to a strong inference of fraudulent intent. AC ¶ 137. Defendant Danziger is alleged to have sold one-third of his shares in NovoCure on January 5, 2023,[24] the day that LUNAR's topline results were announced. *Id.* ¶ 136. However, the AC concedes that the entire sale was made "pursuant to [a] Rule 10b5-1 trading plan[]." *Id.* ¶ 141.[25] "[I]t is well established that trades under 10b-5-1 plan[s] do not raise a strong inference of scienter." *Glaser v. The9, Ltd.*, 772 F. Supp. 2d 573, 592 (S.D.N.Y. 2011) (quotations omitted); *see also, e.g.*, *In re Gildan Activewear, Inc. Sec. Litig.*, 636 F. Supp. 2d 261, 272 (S.D.N.Y. 2009) (dismissing

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Opp. at 44 (arguing that the Individual Defendants' actions can be imputed to NovoCure); Reply at 20–25 (not disputing this argument).

[24] Specifically, Danziger allegedly sold 212,500 shares of NovoCure stock, which amounted to 33.7% of his holdings. AC ¶ 136. His proceeds from the stock sales totaled $23,106,172. *Id.*

[25] Defendants argue that it is premature to dismiss Danziger's claims based on his trading plan because "[t]he existence of a Rule 10b5-1 Trading Plan is an affirmative defense that must be pled and proved." Opp. at 41 (quoting *Plumbers & Pipefitters Nat'l Pension Fund v. Tableau Software, Inc.*, No. 17-cv-5753 (JGK), 2019 WL 2360942, at *6 (S.D.N.Y. Mar. 4, 2019)). "Dismissal under Fed. R. Civ. P. 12(b)(6) is appropriate," however, when "an affirmative defense . . . is clear from the face of the complaint." *Sewell v. Bernardin*, 795 F.3d 337, 339 (2d Cir. 2015) (quotations omitted). The AC affirmatively alleges that Danziger's trades were made pursuant to a Rule 10b5-1 trading plan, AC ¶ 141, so it is clear from the face of the AC that Danziger's trading plan exists, *see Plumbers*, 2019 WL 2360942, at *6.

scienter claims predicated on trades made pursuant to Rule 10b5-1 plans, noting that such trades are "non-discretionary, which undermines any allegation that the timing or amounts of the trades was unusual or suspicious"); *Fishbaum v. Liz Claiborne, Inc.*, No. 98–9396, 1999 WL 568023, at *4 (2d Cir. 1999) (affirming dismissal of securities-fraud claims on scienter grounds, noting that defendants' alleged trades "were not suspicious" as they "appeared to be part of a periodic divestment plan"). "'Although this axiom does not apply where a 10b5-1 plan is entered into or strategically amended to take advantage of an inflated stock price or insider information,' the []AC here 'contains no such allegations' beyond conclusory ones." *In re Plug Power, Inc. Sec. Litig.*, No. 21-cv-2004 (ER), 2022 WL 4631892, at *15 (S.D.N.Y. Sept. 29, 2022) (quoting *Villare v. Abiomed, Inc.*, No. 19-cv-7319 (ER), 2021 WL 4311749, at *21 (S.D.N.Y. Sept. 21, 2021)). The AC merely alleges that "it is plausible" that Danziger's trading plan was amended or adopted before the announcement of LUNAR's topline results, or that NovoCure timed the LUNAR announcement to coincide with a planned sale of Danziger's stock. AC ¶ 141. These allegations are concededly speculative and conclusory, *San Leandro Emergency Med. Grp. Profit Sharing Plan v. Philip Morris Companies, Inc.*, 75 F.3d 801, 813 (2d Cir. 1996) ("Plaintiffs do not . . . enjoy a license to base claims of fraud on speculation and conclusory allegations." (quotations omitted)), and multiple courts have held that they do not suffice to plead that an executive's "stock sales were suspicious or unusual," *Villare*, 2021 WL 4311749, at *21; *accord In re Plug Power*, 2022 WL 4631892, at *15 (finding scienter inadequately pleaded where plaintiff alleged that "it is 'highly plausible'" that trades made pursuant to Rule 10b5-1 plans were made after the plans were "adopted or amended during the Class Period").

Plaintiff's allegations regarding Cordova's trading activity are also insufficient. The AC alleges that Defendant Cordova sold 4.78% of her NovoCure shares over the course of three trades on March 1, 2, and 3, AC ¶ 136, and distinguishes those sales from Danziger's because they were not made pursuant to a Rule 10b5-1 trading plan, *id.* ¶ 142. However, as Plaintiff concedes, *see* Opp. at

42, "the relevant Form-4s that were filed by [NovoCure] with the SEC for these sales by [Cordova] indicate that the sales were executed to cover the tax withholding obligations due upon the vesting of shares of restricted stock." *In re Keryx Biopharmaceuticals*, 2014 WL 585658, at *13. The Form-4s each state that Cordova's stock sales "were mandated by [NovoCure's] award agreement . . . and do[] not represent a discretionary trade by [Cordova]." Brody Decl., Exs. 20–22. "Such sales for tax reasons are not indicative of fraud." *In re Keryx Biopharmaceuticals*, 2014 WL 585658, at *13; *accord In re Bristol-Myers Squibb Litig.*, 312 F. Supp. 2d at 561 (finding stock trades did not suffice to plead scienter because, among other things, "the documents reflecting the Individual Defendants' trading . . . show[ed] a consistent pattern of trading undertaken primarily to make payments required for the exercise of stock options or to pay taxes").

Plaintiff's argument that he has raised a "disputed issue of fact" regarding whether Cordova's stock sales were effected for tax purposes, Opp. at 42 (quotation omitted), ignores that he has "not allege[d] any facts suggesting otherwise." *Fries v. N. Oil & Gas, Inc.*, 285 F. Supp. 3d 706, 720 n.5 (S.D.N.Y. 2018) (finding scienter was not adequately pleaded based on alleged insider stock trading because "SEC filings show that [defendants] sold stocks for tax purposes"). It is true that the Form 4s corresponding to Cordova's stock sales cannot, at this stage, be considered to "establish the truth of the matters asserted therein." Opp. at 43 n.29 (quoting *Pitman*, 2024 WL 964258, at *1 n.3). They are, however, capable of introducing an "opposing inference of nonfraudulent intent" behind Cordova's trades, *Slayton*, 604 F.3d at 775 (alteration omitted); *see In re Keryx Biopharmaceuticals*, 2014 WL 585658, at *13; *In re Bristol-Myers Squibb Litig.*, 312 F. Supp. 2d at 561, which the AC's allegations must equal if Plaintiff is to adequately plead scienter, *Tellabs*, 551 U.S. at 324. The AC's

allegations fall short of doing so because they allege no more than "executive stock sales, standing alone." *Farfetch Ltd.*, 565 F. Supp. 3d at 486–87.[26]

In any event, Cordova sold less than 5% of her shares in NovoCure during the Class Period, a proportion that multiple courts have held is low enough "to militate against an inference of scienter." *In re Gildan Activewear*, 636 F. Supp. 2d at 270–71 (finding that "stock sales amount[ing] to only 22.5% and 4.9%" of defendants' holdings did not support a strong inference of scienter); *In re Iconix Brand Grp.*, 2017 WL 4898228, at *15 (same, where challenged stock sale "amounted to less than 9%" of defendant's holdings); *Acito v. IMCERA Grp., Inc.*, 47 F.3d 47, 54 (2d Cir. 1995) (similar, where defendant sold "less than 11% of his holdings"). Nor are Cordova's stock sales alleged to have been timed in accordance with any specific disclosures, a point which cuts against the notion that they were "calculated to maximize [her] personal benefit from undisclosed information." *Meyer v. Organogenesis Holdings Inc.*, 727 F. Supp. 3d 368, 395 (E.D.N.Y. 2024). Though her sales took place during the Class Period, they "pre-dated and post-dated [each] alleged actionable statement[]" by at least one week, *id.*; AC ¶ 136, and her "last alleged sale occurred more than [three] months prior to the end of the Class Period," *Meyer*, 727 F. Supp. 2d at 395; AC ¶ 136; *accord City of Taylor Gen. Emps. Ret. Sys. v. Magna Int'l Inc.*, 967 F. Supp. 2d 771, 800 (S.D.N.Y. 2013) (finding stock sales within class period were not unusual or suspicious, observing that the sales were not effected "at the end of the putative class period, when insiders would have rushed to cash out" (quotations omitted)).[27]

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[26] For these reasons, among others, the cases Plaintiff relies on are inapplicable. In *Fresno Cnty. Employees' Ret. Ass'n v. comScore, Inc.*, the individual defendants had sold 92%, 83%, and 68% of their shares, and only argued that a portion of their sales were made to satisfy tax liabilities. 268 F. Supp. 3d 526, 555 (S.D.N.Y. 2017). And in *City of Warren Police & Fire Ret. Sys. v. World Wrestling Ent. Inc.*, the defendant had sold his shares "only [a] few days before" a lucrative agreement was set to expire without renewal, unbeknownst to investors, and his alternative explanation for the sales was merely that he intended "to fund the creation of an additional sports league." 477 F. Supp. 3d 123, 137 (S.D.N.Y. 2020).

[27] The AC also alleges stock sales by five other "NovoCure insiders" during the Class Period. Opp. at 39; AC ¶ 136. Those sales do not support a strong inference of scienter here, as "Plaintiff[] offers no reason why [the other insiders' trades] would be relevant, let alone why [they] support[] an inference of scienter as to Defendants." *Constr. Laborers Pension Tr. for S. California v. CBS Corp.*, 433 F. Supp. 3d 515, 546 (S.D.N.Y. 2020); *accord In re Philip Morris Inc. Sec. Litig.*,

Plaintiff's motive theory is further undermined by the fact that Defendant Doyle, NovoCure's Executive Chairman, is not alleged to have sold any stock at all. *See* Opp. at 43. As NovoCure's chairman, and as the individual who made most of the alleged misstatements, Doyle, "if anyone, was surely well-positioned to reap profits from insider knowledge." *In re Keyspan Corp. Sec. Litig.*, 383 F. Supp. 2d 358, 383–84 (E.D.N.Y. 2003); *accord In re Take-Two Interactive Sec. Litig.*, 551 F. Supp. 2d 247, 278 (S.D.N.Y. 2008) (finding scienter not adequately pleaded where "the defendants most intimately involved" were not alleged to have sold any shares during the class period). Plaintiff argues that Doyle's choice not to sell any NovoCure stock is irrelevant, *see* Opp. at 43, but as Plaintiff elsewhere concedes, Plaintiff's entire theory of fraud in this case is based on a temporary inflation of NovoCure's stock, *see id.* at 44 (arguing that "a brief fraud is still a fraud," and that "Danziger and Cordova [sold] their stock at artificially inflated prices"). Defendants are not alleged to have misrepresented or omitted any LUNAR data in their corrective disclosures at the June conference, nor are they alleged to have intended to do so at any point during the Class Period. Doyle's choice not to divest of any of his holdings in NovoCure during the Class Period, therefore, is plainly "significant." *In re Keyspan Corp. Sec. Litig*, 383 F. Supp. 2d at 384; *see also San Leandro*, 75 F.3d at 814 (finding scienter not adequately pleaded where one executive sold shares during the class period because "the fact that other defendants did not sell their shares during the relevant class period sufficiently undermines plaintiffs' claim regarding motive").

For these reasons, the AC's allegations, taken together, fail to raise an inference of scienter based on Defendants' motive to commit fraud.

ii. Conscious Misbehavior or Recklessness

437 F. Supp. 3d at 361 (finding scienter not adequately pleaded where allegations regarding defendants' stock trades were insufficient to plead motive and "Plaintiff's only other allegations regarding trading of stock involve non-Defendants").

Plaintiff's second set of scienter-related allegations, that Defendants "knew and/or recklessly disregarded" information about LUNAR that was contrary to their public statements, *see* AC ¶¶ 127–35, also fail to raise a strong inference of scienter. As an alternative to pleading that Defendants had "a motive and opportunity to commit fraud," Plaintiff may adequately plead scienter by "alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness." *Acito*, 47 F.3d at 52. Having failed to adequately plead motive, however, "the strength of [Plaintiff's] circumstantial allegations must be correspondingly greater." *Kalnit*, 264 F.3d at 142. Plaintiff's circumstantial allegations do not meet this standard.

Plaintiff does not appear to argue that the AC adequately alleges "conscious misbehavior" on the part of any defendant. *See* Opp. at 36; *Acito*, 47 F.3d at 52. Instead, he argues that the AC provides sufficient circumstantial allegations to plead a "recklessness" theory of scienter, Opp. at 36–39 (collecting the AC's "allegations of recklessness"), because it alleges that Defendants possessed and reviewed the LUNAR data before the Class Period, *id.* at 36–37, and recklessly disregarded the information within it that "contradict[ed] their public statements," *id.* at 36 (quoting *Novak*, 216 F.3d at 308). As discussed, recklessness in this circuit means "conscious recklessness—*i.e.*, a state of mind *approximating actual intent*, and *not merely a heightened form of negligence*." *S. Cherry St.*, 573 F.3d at 109 (quoting *Novak*, 216 F.3d at 312) (emphasis in original); *see also In re Advanced Battery Techs., Inc.*, 781 F.3d 638, 644 (2d Cir. 2015) (observing "[i]n the securities fraud context, recklessness [is] not merely a heightened form of negligence" (quotations omitted)). To meet this standard based on a contention that "defendants had access to contrary facts," a plaintiff "must specifically identify the reports or statements containing this information." *Novak*, 216 F.3d at 309; *accord, e.g.*, *Pitman*, 2024 WL 964258, at *20 (rejecting scienter claims that defendants "had access to . . . information and a duty to monitor" but "made statements in contravention of this information" because plaintiff failed to allege that defendants reviewed "specific studies" putting them on "notice of contradictory

information"); *Plumbers & Steamfitters Loc. 773 Pension Fund v. Canadian Imperial Bank of Com.*, 694 F. Supp. 2d 287, 299 (S.D.N.Y. 2010) (dismissing claims for failure to plead scienter, observing that "Plaintiffs should, but do not, provide specific instances in which Defendants received information that was contrary to their public declarations").

The AC does not provide allegations of "specific instances in which Defendants received information that was contrary to their public statements," *Plumbers & Steamfitters*, 694 F. Supp. at 299, and without such allegations, the AC does not "raise[] an inference of scienter based on knowledge of or access to information demonstrating the inaccuracy of [Defendants'] public statements," *Teamsters Loc. 445 Freight Div. Pension Fund v. Dynex Cap. Inc.*, 531 F.3d 190, 196 (2d Cir. 2008). The AC rests largely on generalized and conclusory allegations that Defendants had access to the alleged problems with LUNAR's data when they made their statements, *see, e.g.*, AC ¶¶ 128 ("Defendants, by virtue of their receipt of information reflecting the true facts regarding NovoCure, . . . made them privy to confidential proprietary information concerning NovoCure."), 129 ("Defendants knew and/or recklessly disregarded the false and misleading nature of the information which they caused to be disseminated to the investing public."), 130 ("There is no reasonable dispute that Defendants knew about the problems with the LUNAR trial data throughout the Class Period."), as well as allegations that the Individual Defendants had access to contradictory LUNAR data "by virtue of their high-level positions" and "direct[] participat[ion] in the management of [NovoCure]," *id.* ¶ 130. It is well-settled, however, that "to establish an inference of scienter, Plaintiff must do more than allege that the Individual Defendants had or should have had knowledge of certain facts contrary to their public statements simply by virtue of their high-level positions." *Lipow v. Net1 UEPS Techs., Inc.*, 131 F. Supp. 3d 144, 163 (S.D.N.Y. 2015) (collecting cases).

The AC also alleges that Defendant Doyle publicly "acknowledged" Defendants' knowledge of the "problems with the LUNAR trial data throughout the Class Period," AC ¶ 132, but the AC's factual allegations do not support this contention. The AC alleges merely that Doyle stated, during a February 23, 2023 conference call, that "NovoCure was 'continu[ing] to analyze the data in preparation for a full presentation and publication,'" and that NovoCure "was 'in the process of both preparing the [LUNAR] publication and submitting the abstract for presentation at an upcoming medical conference.'" *Id.* (alterations in original). Doyle's statements are too indeterminate to raise a strong inference that he, or any of the other defendants, had received any particular indication during NovoCure's "continuing" analysis that might have contradicted their public statements about LUNAR. *See Novak*, 216 F.3d at 309 ("Where plaintiffs contend defendants had access to contrary facts, they must specifically identify the reports or statements containing this information."). His statements do not support an inference, for example, that there were "any [internal] disputes about the validity" of LUNAR's topline results, or that there "exist[ed] internal reports that might have led defendants to challenge" their public statements about LUNAR. *Abely*, 2013 WL 2399869, at *19; *see also Steinberg v. Ericsson LM Telephone Co.*, No. 07-cv-9615 (RPP), 2008 WL 5170640, at *13–14 (S.D.N.Y. Dec. 10, 2008) ("[T]he Complaint identifies none of this adverse information other than stating, generically, that it was contained in various 'internal corporate documents, . . . and 'internal non-public reports' provided to Defendants."); *In re Iconix*, 2017 WL 4898228, at *18 (dismissing scienter allegations where "the Amended Complaint cite[d] no internal reports, documents, or communications that shed light on Defendant's knowledge of or conduct concerning the Company's accounting practices," nor "statements of confidential witnesses addressing these issues").

To the contrary, Doyle's alleged statements merely make "broad references to [LUNAR's] raw data," without "even [stating] that these data had been collected into reports." *Abely*, 2013 WL

2399869, at *19 (quoting *Teamsters*, 531 F.3d at 196). The Second Circuit has repeatedly held that such allegations are inadequate to allege scienter based on knowledge or access to contrary facts, *Teamsters*, 531 F.3d at 196, as they do not raise a strong inference that the speaker knew of the alleged contrary facts within the data when speaking, *see Novak*, 215 F.3d at 309; *see also San Leandro*, 75 F.3d at 812–13 ("References to unreleased or internal information that allegedly contradicts defendants' public statements should indicate such matters as who prepared the projected figures, when they were prepared, how firm the numbers were, or which company officers reviewed them." (quotations and alterations omitted)). Considered together with the AC's "fail[ure] to allege scienter adequately by demonstrating motive and opportunity to defraud," the AC's reliance on Doyle's broad statements regarding NovoCure's "continuing" analysis of the LUNAR data falls short of adequately pleading scienter. *Kalnit*, 264 F.3d at 142 ("Where motive is not apparent, . . . the strength of the circumstantial allegations must be correspondingly greater." (quotation omitted)).

Moreover, the AC's allegation that Defendants were "planning for . . . three additional pivotal trials in NSCLC" as they were announcing LUNAR's topline results, AC ¶ 134, does not support an inference of scienter because there is nothing unusual about a developer of medical devices like NovoCure planning more than one trial to test a device's efficacy, *see Tellabs*, 551 U.S. at 314 (the inference of scienter in securities-fraud cases "must be . . . at least as compelling as any opposing inference of nonfraudulent intent"). The AC alleges, without elaboration, that Defendants' preparation for more trials is evidence that they knew that TTFields "would not be widely adopted by the medical community until NovoCure was able to complete additional, well designed and successful pivotal trials." AC ¶ 134. As discussed, however, immediate industry or commercial uptake is not necessarily the measure of success for a clinical trial, and Defendants disavowed the notion that the announcement of LUNAR's results would lead to the immediate uptake of TTFields therapy in treating NSCLC. *See, e.g.*, *id.* ¶ 90. The AC's conclusory allegation

that the existence of additional trials establishes motive, without more, does not support a strong inference of scienter.

Finally, the AC's allegation that that NovoCure's Chief Medical Officer ("CMO") was "sudden[ly] terminat[ed]" twelve days after LUNAR's topline results were announced, AC ¶ 135, does not raise inference of scienter because the AC provides no allegations connecting the termination to the fraud alleged in this case. "Terminations and resignations of corporate executives are insufficient alone to establish scienter," *Woolgar v. Kingstone Companies, Inc.*, 477 F. Supp. 3d 193, 240 (S.D.N.Y. 2020), as "there are any number of reasons that an executive might resign, most of which are not related to fraud," *Das v. Rio Tinto PLC*, 332 F. Supp. 3d 786, 815 (S.D.N.Y. 2018) (quoting *In re BISYS Sec. Litig.*, 397 F.Supp.2d 430, 446 (S.D.N.Y. 2005)). A termination that is not "link[ed] . . . to the alleged fraud" with "additional factual allegations" is "insufficient to raise a strong inference of scienter." *In re UBS AG Sec. Litig.*, No. 07-cv-11225 RJS, 2012 WL 4471265, at *18 (S.D.N.Y. Sept. 28, 2012), *aff'd sub nom. City of Pontiac*, 752 F.3d 173 (quoting *In re PXRE Group Ltd., Securities Litigation*, 600 F. Supp. 2d 510, 545 (S.D.N.Y. 2009)). Here, other than describing the event as "sudden," the AC provides no allegations connecting the termination of NovoCure's CMO to the fraud alleged. AC ¶ 135. The CMO is not even mentioned anywhere else in the AC. Without more, his termination is insufficient to plead an inference of scienter. *See, e.g.*, *In re UBS AG Sec. Litig.*, 2012 WL 4471265, at *18 (finding the alleged "forced resignations and terminations of key . . . personnel" did not support a strong inference of scienter because the complaint did "not state any facts to indicate that [the] departure[s] [were] a result of any knowledge of alleged fraudulent activities").

In sum, having analyzed and considered "all the allegations holistically," the Court finds that the AC fails to raise a strong inference of scienter, one that is "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs*, 551 U.S. at 314, 326.

V. LEAVE TO AMEND

Plaintiff has requested leave to amend the AC if his claims are dismissed. Opp. at 45 n.32. The Federal Rules of Civil Procedure provide that courts should "freely give" leave to amend "when justice so requires," Fed. R. Civ. P. 15(a)(2), and "[d]istrict courts typically grant plaintiffs at least one opportunity to plead fraud with greater specificity when they dismiss under Rule 9(b)." *ATSI*, 493 F.3d at 108 (citation omitted). Accordingly, the amended complaint is dismissed without prejudice. Within twenty-one days, Plaintiff may file a second amended complaint to cure the deficiencies identified in this opinion.

VI. CONCLUSION

For the foregoing reasons, Plaintiff's motion to strike is DENIED and Defendants' motion to dismiss is GRANTED. The Clerk of Court is directed to terminate the motions pending at Dkt. Nos. 63 and 71.

SO ORDERED.

Dated: March 18, 2025
New York, New York

GREGORY H. WOODS
United States District Judge